Atherosclerosis Risk in Communities Study Protocol

Manual 6a

Ultrasound Assessment: Scanning Procedures

Visit 3

Version 3.0

January 1995

For Copies, Please Contact
ARIC Coordinating Center
Department of Biostatistics (CSCC)
University of North Carolina at Chapel Hill
CB# 8030, Suite 203, NationsBank Plaza
Chapel Hill, NC 27514

FOREWORD

This manual, entitled Ultrasound Assessment: Scanning Procedures is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 15. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Component Procedures
3	Cohort and Community Surveillance
4	Pulmonary Function Assessment - (Retired)
5	Electrocardiography
6	Ultrasound Assessment a. Ultrasound Scanning Procedures b. Ultrasound B-mode Image Reading Protocol c. Distensibility Scanning Protocol - (Retired) d. Distensibility Reading Protocol - (Retired)
7	Blood Collection and Processing
8	Lipid and Lipoprotein Determinations
9	Hemostasis Determinations
10	Clinical Chemistry Determinations - (Retired)
11	Sitting Blood Pressure
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13	Magnetic Resonance Imaging a. Magnetic Resonance Imaging Protocol b. Magnetic Resonance Imaging Reading Protocol
14	Retinal Photography
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1. INTRODUCTION

The ultrasound examination of the ARIC cohort participants consists of the following components: (1) ultrasonic imaging of the carotid arteries in the neck and (2) monitoring of arterial blood pressure throughout the ultrasound examination. This protocol details both types of procedures. Additional instructions for monitoring arterial blood pressure are detailed in the Dinamap Service Manual, which is included with each Dinamap (Model 1846SX) unit. Interpretation of the ultrasound examination performed at the Ultrasound Reading Center (URC) is described in the Ultrasound Assessment Part 2: Reading Protocol.

2. SELECTION OF ULTRASOUND SYSTEM

The ultrasound system selected for use in the ARIC Visit 1 (1987-1989) and Visit 2 (1990-1992) exams was the Biosound 2000 II. Selection of the Biosound 2000 II was based on the results of a series of detailed protocols performed on systems provided by four different manufacturers, and included in-vitro tests on excised arteries, measurement of the transmitted pressure pulse with a miniature hydrophone transducer, routine system performance measurements on phantom test objects, and in-vivo evaluations which included considerations of ease of use by the sonographer. The ultrasound system selected for ARIC Visit 3 (1993-1995) is the Biosound Phase 2. The Biosound Phase 2 is the updated model of the Biosound 2000 II. It was chosen because the older model is no longer manufactured and maintenance of a high performance level in the 2000 II would be increasingly difficult to achieve during this Visit. The Phase 2 performs essentially the same as the Biosound 2000 II. The improvements include a lighter transducer probe, an extended (deeper) field of view, improved gray scale presentation and a closer adherence to the NTSC standards for video signals.

3. ULTRASOUND AREA INSTRUMENTATION

The ultrasound area instrumentation consists of a Biosound Phase 2 ultrasound imaging system, an NEC PC 1/2" Video Cassette Recorder, an RMI 414B Tissue Mimicking Ultrasound Phantom, a 486-SX computer, an IBM-XT computer, a Dinamap automated blood pressure machine and a computer software study flow program. The equipment was designed and selected to assist the sonographer in adhering to the protocol steps. Figures are presented at the end of Section 4, including a "Cabling Connections Reference". A brief description of each piece of equipment follows.

3.1 The Biosound Phase 2 Ultrasound Imaging System

The Biosound Phase 2 system is a high resolution ultrasound imaging system designed for relatively shallow anatomical structures such as the extracranial carotid arterial system. Images of the arteries are obtained using a nominal 8 MHz transducer driven by a motor in a sector scan format. The sector scan format is presented in a rectilinear format with a nominal lateral view of 2 cm and a depth of 5 cm.

In addition to the B-mode image, Doppler signals from the arteries can be obtained, processed and displayed in a frequency versus time format. The Doppler information is used primarily for arterial identification.

An 1/2" sVHS video cassette recorder (VCR) is connected to the Biosound Phase 2. The VCR records the ultrasound video information coming from the video channel onto the video cassette.

3.2 The Video Cassette Recorder

The video recorder is an NEC 1/2" sVHS PC-VCR. It was chosen to provide superior image quality cassettes. The sVHS cassettes are sent to the Ultrasound Reading Center for interpretation.

3.3 The RMI Tissue-Mimicking Ultrasound Phantom

A modified RMI 414B tissue mimicking ultrasound phantom with water trough attachment is used periodically for performance checks on the Biosound Phase 2. The phantom has arterial mimicking targets of various diameters and depths. These targets can be scanned from both longitudinal and transverse directions, and the images and video information can be evaluated to assess system performance. The images are recorded on 1/2" sVHS video cassettes and sent to the Ultrasound Reading Center.

3.4 The 486-SX Computer

The 486-SX computer is used for multiple purposes in the ultrasound area. The computer interacts with the sonographer and ultrasound area equipment to perform the following tasks:

a. To obtain participant data, such as identification number, birth date, race, and gender.
b. To establish files for participant data with appropriate names and file extensions.
c. To keep a record of the study steps performed, including quality assurance studies, from the study flow program.
d. To determine the frequency of quality assurance studies and the arterial sites where the quality assurance studies are performed.
e. To record data on hard disk for temporary storage and on diskette to send to the Ultrasound Reading Center.

The sonographer interacts with the computer during the initial questionnaire and at the completion of the study. The study flow program interfaces with the IBM-XT to control the Dinamap blood pressure monitor and to control the VCR operation. Instructions on the computer screen from the study flow program determine when to take blood pressures manually. At other times, blood pressures are taken automatically by the Dinamap under computer control.

The computer controls the PC-VCR video cassette recorder. The primary purpose of the PC-VCR is to record the B-scan video images for reading at the Ultrasound Reading Center; however, it performs additional tasks. It records audio comments of the sonographers as the scan progresses for the ultrasound readers to aid them in the interpretation of recorded B-mode images. As the B-scan images are being recorded, the PC-VCR labels the tape with an address on a frame-by-frame basis. The frame address is used at the reader station for frame identification and to compare frame selection among readers.

A sonographer box transmits signals to the 486 computer. These signals, initiated either by push buttons or foot switches, advance the study flow program through the steps of the scanning program.

When the sonographer has acquired the best images obtainable at a site, the sonographer footswitch is pressed and detected by the computer. The frame address on the video tape is read and stored, and an audio tone is placed on the audio channel. The frame address is later placed in a file for use at the reader station. The audio tone identifies portions of the video cassette that the sonographer feels are the best obtainable views of a site and aids readers and/or reviewers in finding particular sections on the cassette.

3.5 The Study Flow Program

The B-mode ultrasound examination consists of bilateral carotid artery studies and involves a minimum of 10 steps, performed in a similar sequence for each participant. A study flow program assists the sonographer during the examination by formatting and displaying computer screens showing steps to be completed and steps which have been completed. A manual override box is available for making any changes in the programmed sequence.

3.6 IBM-XT Computer

The IBM-XT computer is used to initiate the Dinamap for blood pressure measurements. All measurement results are stored on the IBM-XT until the ultrasound exam is over. The results are stored on a 5 1/4" floppy disk. That floppy is inserted into the **A: drive** on the 486 computer and transferred to a 3 1/2" floppy for transfer to the Ultrasound Reading Center.

3.7 Dinamap Automated Blood Pressure Apparatus

A series of blood pressure measurements is made during the ultrasound examination. The purposes are to provide baseline supine, seated, and standing blood pressure measurements and to estimate an ankle-arm index.

Blood pressure is measured using the Dinamap Model 1846 SX, an automated, oscillometric device. The Dinamap Operation Manual should be read carefully before performing the blood pressure measurements. The timing of blood pressure measurements and the sequencing of the Dinamap Model 1846 SX are determined by the IBM-XT.

The Dinamap Service manual is included with each machine at the time of purchase. If that manual is lost, another can be ordered from the Dinamap zone office.

4. EQUIPMENT MAINTENANCE

Equipment maintenance is performed periodically. Detailed records of maintenance are to be kept at each field center by the chief sonographer.

4.1 Biosound Phase 2 Ultrasound Imaging System

Each field center is required to have Biosound representatives perform a preventive maintenance check four times a year, and to send copies of all Biosound reports to the Ultrasound Reading Center. More frequent service visits may be required if any problems occur between scheduled preventative maintenance visits.

The air filter on the Biosound Phase 2 is removed and cleaned monthly. This helps to encourage air flow to keep the equipment cool and operating more reliably.

The transducer head is to be examined for air bubbles daily before scanning is attempted. Follow Biosound procedures to remove air bubbles.

4.2 Video Cassette Recorder

The Video Cassette Recorder should be cleaned every six months by a Biosound technician during one of their preventive maintenance visits to the field center.

4.3 RMI 414 B Tissue Mimicking Ultrasound Phantom

The RMI 414B phantom is checked weekly to be sure all seals are tight and that the tissue mimicking gel inside has not dried out. Proper care and maintenance of the test phantom is described in the instruction manual accompanying the phantom. The phantoms are stored in an airtight, resealable plastic container. A few drops of water or a wet sponge should be added to this container before sealing to minimize desiccation of the tissue mimicking material. Phantom specifications are found in the phantom instruction manual.

4.3.1 Ultrasound Equipment Performance Check

An ongoing quality assurance check of Biosound instruments is performed twice a month at each field center. This is accomplished by a scan of identical RMI Tissue Mimicking Phantoms. The scans are sent to the Ultrasound Reading Center for evaluation and consist of one scan of a 6 mm diameter simulated vessel within the phantom and one scan of a set of filaments within the phantom.

The following instrument performance protocol is done by a certified sonographer at each field center on the second and fourth Wednesdays after the Biosound ultrasound system has been permitted to warm up for at least 30 minutes. In addition, the procedure is <u>always repeated</u> after the following:

a. After a manufacturer's service call is performed on the Biosound instrument,
b. After the transducer is repaired or replaced.

A log is maintained to insure these tests are performed per the above schedule.

The scan of identical phantoms at each field center provides data for an ongoing quality assurance program to monitor the performance of each Biosound instrument. Through this program, uniform standards are maintained throughout the project.

The RMI 414B ultrasound phantom is placed upright on the examination table with the LONG side of the rectangular case parallel to the longer side of the table. The end of the phantom containing the filaments ranging from 0.5 to 4.0 cm should be positioned closest to the head of the table. (Figure 9).

The top surface of the phantom is cleaned with a damp cloth or paper towel to remove residue. The water tray on the top of the phantom is half-filled with tap water to permit efficient coupling of the ultrasound transducer to the tissue equivalent medium. DO NOT USE GEL AS THE COUPLING MEDIUM. Minimal pressure is exerted on the phantom surface with the transducer throughout the scan. Excessive pressure or gel on the phantom surface can cause severe damage to the phantom.

A two minute segment of B-mode phantom images is recorded during this check as described below. Use a separate sVHS video tape to record only phantom images. Selected frames are read at the Ultrasound Reading Center to quantitatively document the ultrasound system imaging characteristics.

Set the VCR display screen to be sure the channel display is set at L. If the "L" is not displayed, press the up and down arrow keys on the VCR keyboard labeled "Channel" until it does appear.

Press the letter "D" on the Phase 2 keyboard and wait for Main Menu to appear on the bottom of the right monitor screen of the Phase 2.

Select PROBE 1, located on the Phase 2 keyboard.

Make sure the "LUT LN" setting is on the third line of the right Phase 2 monitor. If the "LUT LN" is not present, press the blue IMAGE PROCESS key and select "LINEAR". "LUT LN" will be displayed in the upper right portion of the screen. (Note: The Menu keys are the five black keys located at the top of the Phase 2 keyboard.)

Check the image orientation. It must be in standard mode. At the main menu, press the Image control option, then press the TGC option. Last, press the Standard option. Once these steps are completed return to the main menu by pressing Escape until the main menu appears.

To enter phantom information on the tape menu screen, do the following:

a. Press the fourth menu key to display the Setup menu.
b. Press the first menu key to display Patient menu. Press the first menu key again. NAME becomes highlighted. Type in the phantom serial number and the transducer serial number, separated by a space. Press the RETURN key.
c. Press second menu key for Participant ID information. Type in the field center location and sonographer ID number. Press the RETURN key to return to the Patient menu.
d. When all entries have been made, press the ESCAPE key twice to reach the Main Menu.

The Doppler cursor can be removed by pressing the green DOP CURSOR key located on the Phase 2 keyboard. This key may be toggled ON or OFF. Place Doppler cursor in the middle section of the screen.

To put the crosshair on the image to define the vertical center of the screen for landmark identification, do the following:

a. Press the third menu key to display the Calculate menu.
b. Press the first menu key to display Distance menu.
c. Press the first menu key again for "Distance plus". the cursor will appear in the upper portion of the screen.
d. Move the cursor to the vertical center position identified by the doppler cursor, and make certain it is kept in the vertical center when it is moved during the performance check. The transducer power is activated, and the system is placed in the normal B-scan imaging mode. The transducer focus setting is placed in the 3.0 cm focus position (Far focus).
e. Adjust video gain to 50% and adjust TGC settings for optimal imaging.

The sonographer enters the RECORD mode by turning off the pause switch on the NEC PC-VCR, and scans the phantom. Throughout the scan, exert only minimal pressure on the phantom surface with the transducer. To obtain the images in this procedure the long dimension of the white transducer plate is parallel to the long dimension of the phantom. The sonographer obtains a cross-sectional view of the most superficially (2 cm depth) located simulated vessels and then positions the larger (6 mm diameter) of the three vessels in the vertical center of the screen as confirmed by the cursor position. Toggle the Doppler cursor OFF. The crosshair should be contained well within the outline of the vessel, insuring that it does not obscure the reflections from the near or far walls (Figure 10). When a satisfactory image is seen on the screen, mark this point on the tape for the Ultrasound Reading Center.

The sonographer moves the transducer toward the head of the table in order to view the set of filaments ranging from 0.5 to 4.0 cm. These are also viewed in cross-section, making certain the transducer focus setting is in the 3.0 cm position. Using the crosshair as a guide, the filaments are lined up so that they are centered horizontally across the center of the screen (Figure 11). The cursor is positioned in the middle of the screen, taking care to avoid obscuring any of the filament reflections. The reflections of the deeper filaments will have gaps in them due to shadowing caused by the filaments superficial to them (Figure 11). Those gaps are used as an aid in lining up the filaments properly. When a satisfactory image is seen, the select footswitch to mark this image.

This concludes the weekly instrument performance test on the RMI phantom. The water is carefully removed from the phantom, and the phantom is returned to its storage location in the manner described in Section 4.3.

Each phantom tape is labeled according to the following format:

PHANTOM - F- 93 - 03 - 12 - 001
F = the field center code
93 = the year the tape is started
09 = the month the tape is started
12 = the month the tape is complete (left blank until tape is full)
001 = sequential number of each tape (begins with 001 at each field center)

This label should be placed on the video cassette. The video cassette box should also be labeled accordingly. At the end of each week, the cassette is shipped to the Ultrasound Reading Center with the current shipment of B-mode tapes. A second tape is used to record the next week's scan(s) and a third tape for the week after. These three tapes will be rotated until they are full. Completed tapes will be stored at the Ultrasound Reading Center, and another tape will be started at the field center when this occurs.

4.3.2 Additional Points to Remember

While scanning the phantoms, the sonographer is to look for changes in the following:

- shape of simulated vessels (these should appear circular)
- the gain settings required to obtain adequate images, or
- the focal settings required to obtain images.

If the sonographer notices changes in any of these conditions, he/she should do the following:

- Contact the Biosound technician authorized to work with this instrument (Bob Nitsch 800/428-7378) and
- Contact the Ultrasound Coordinator at the Ultrasound Reading Center at (910)759-2137 and report the action to be taken by the Biosound technician

  Note: Other Biosound personnel should not work on the instrument unless specifically authorized by Mr. Nitsch.

If the phantom surface begins to cave in or pucker:

- Call the supplier to arrange service.
- Notify the Ultrasound Reading Center Coordinator immediately.

Following any service call, the chief sonographer is to send a copy of the service report to the URC Coordinator and/or Phantom reader.

It is important to vary the location of the transducer within the prescribed areas on the phantom when doing the scans, i.e., position in the center, left of center, right of center, in order to extend the life of the phantom.

4.4 486-SX Computer

In general, no maintenance is required on the computer with the exception that, if there is one, the clock battery is replaced annually. In case of any system problems, the field center data coordinator contacts the appropriate authorized repair facility.

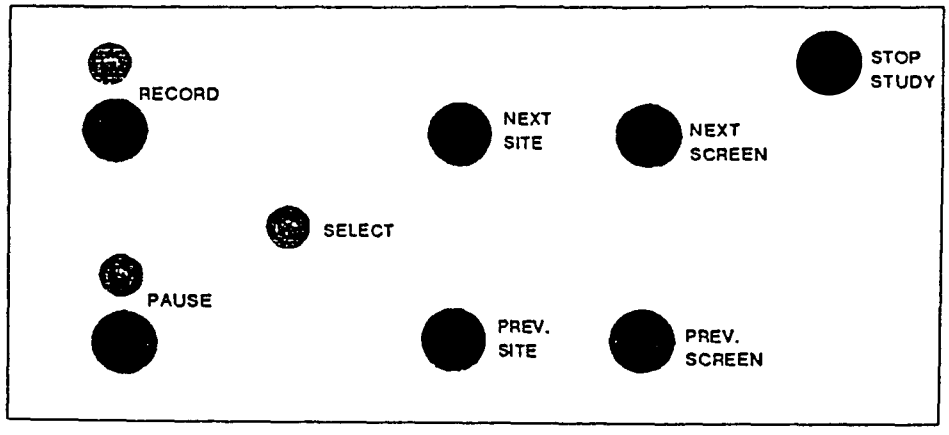
4.5 IBM-XT Computer

In general, no maintenance is required on the computer with the exception that, if there is one, the clock battery is replaced annually. In case of any system problems, the field center data coordinator contacts the appropriate authorized repair facility.

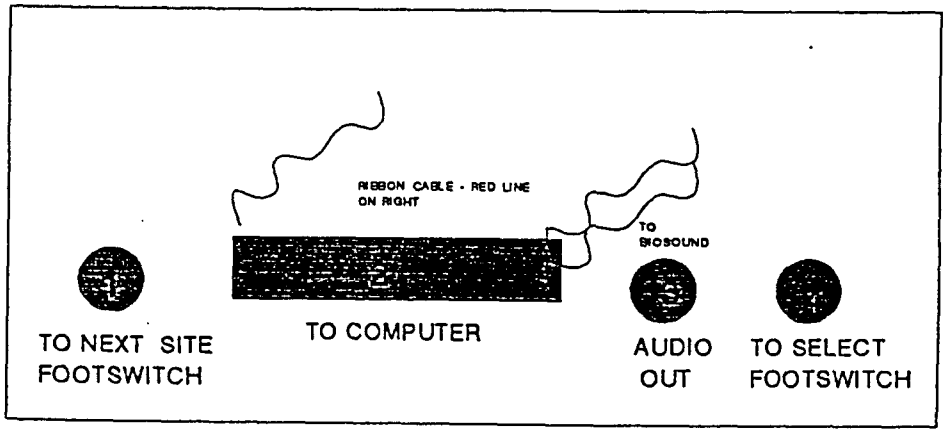
4.6 Dinamap Automated Blood Pressure

It is recommended that the Dinamap Model 1846 SX be calibrated every six months using calibration procedures in the Dinamap instruction manual. Copies of calibration reports are to be forwarded to the Ultrasound Reading Center.

SONOGRAPHER'S BOX



FRONT PANEL



REAR PANEL

Figure 1. Ultrasound Assessment Equipment: Sonographers's Box

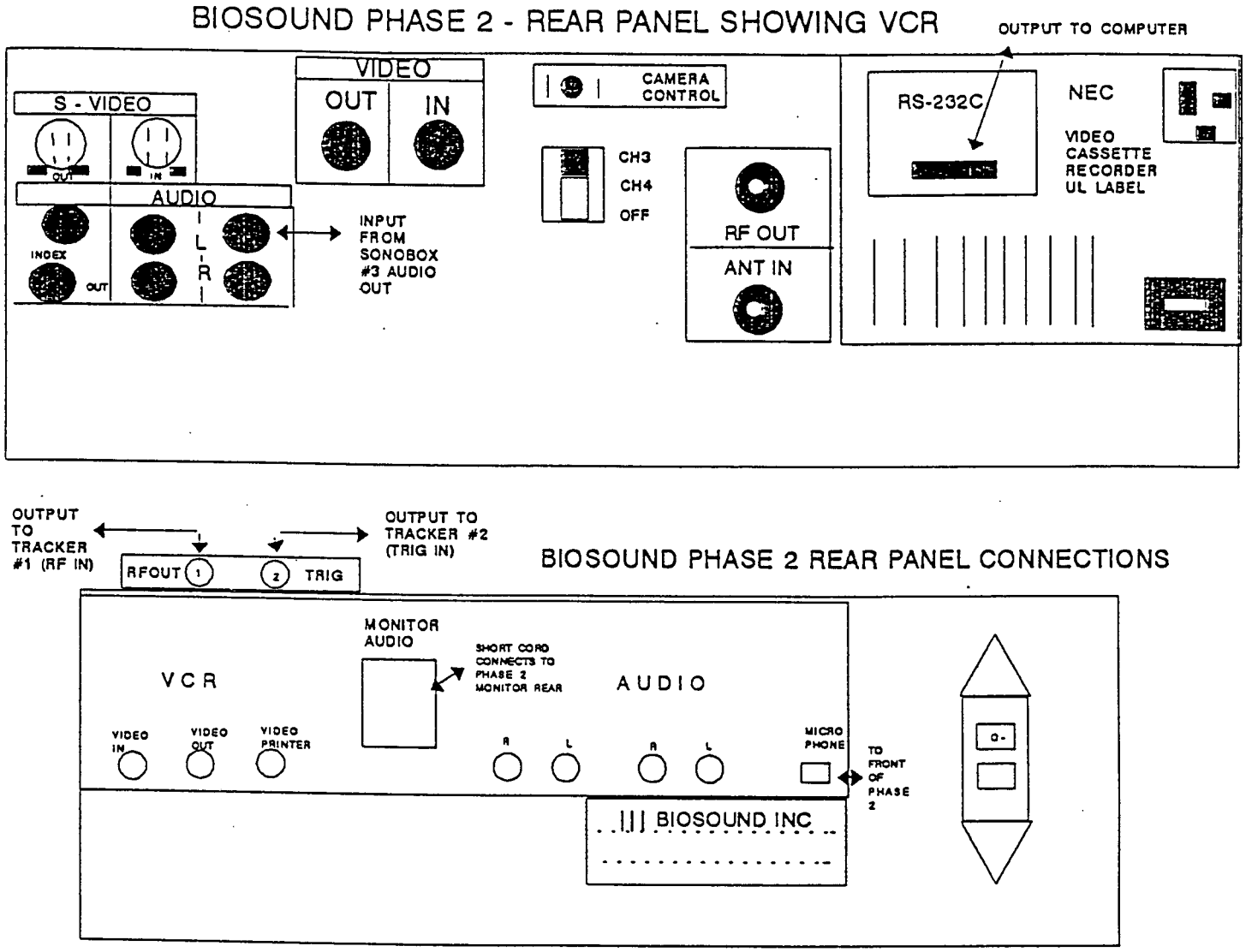


Figure 2. Ultrasound Assessment Equipment: Biosound Phase 2 VCR

REAR OF BIOSOUND PHASE 2 - VIDEO PRINTER

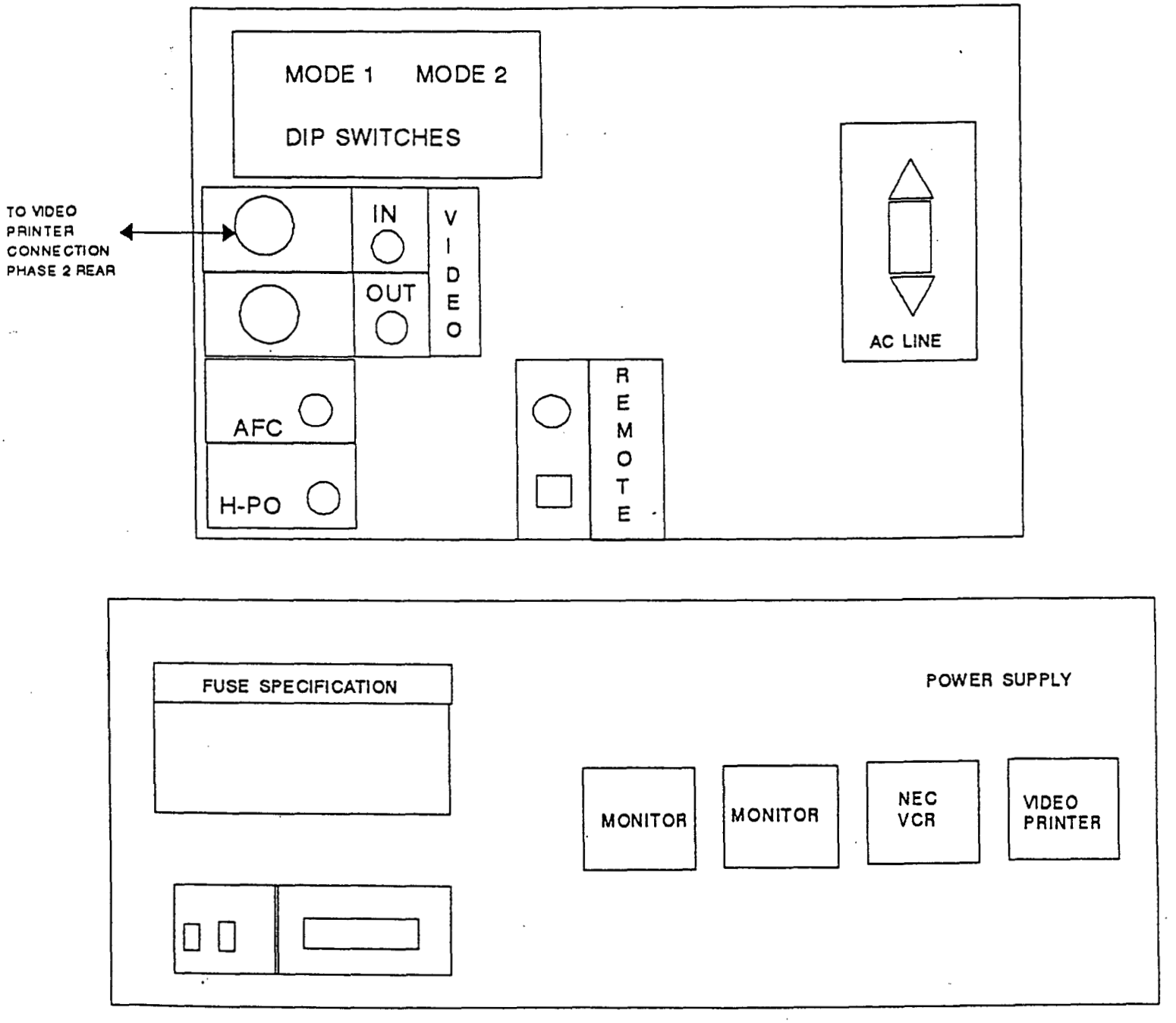
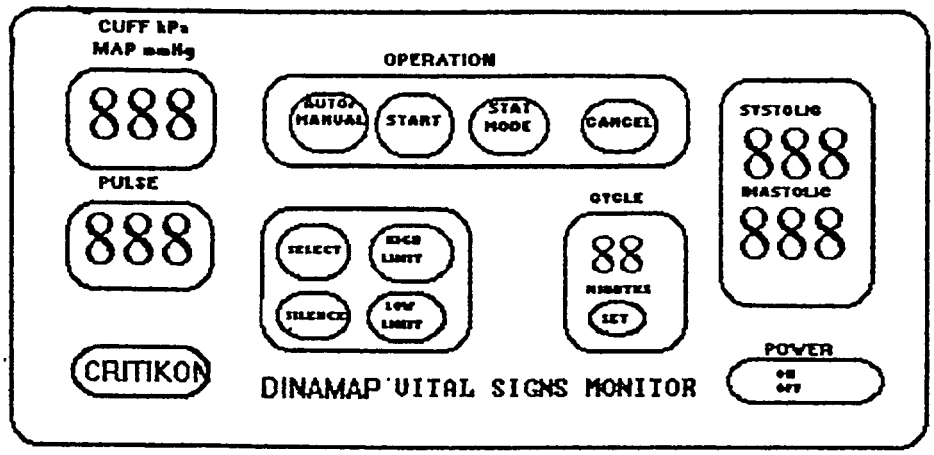


Figure 3. Ultrasound Assessment Equipment: Biosound Phase 2 Printer



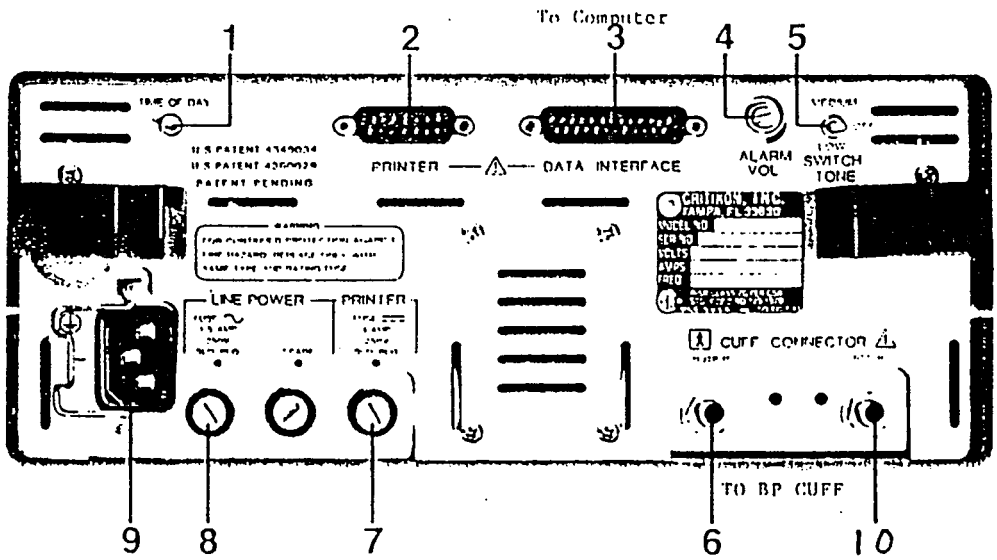


Figure 4. Ultrasound Assessment Equipment: DINAMAP Monitor

Computer - PC 486
Facing Rear Panel

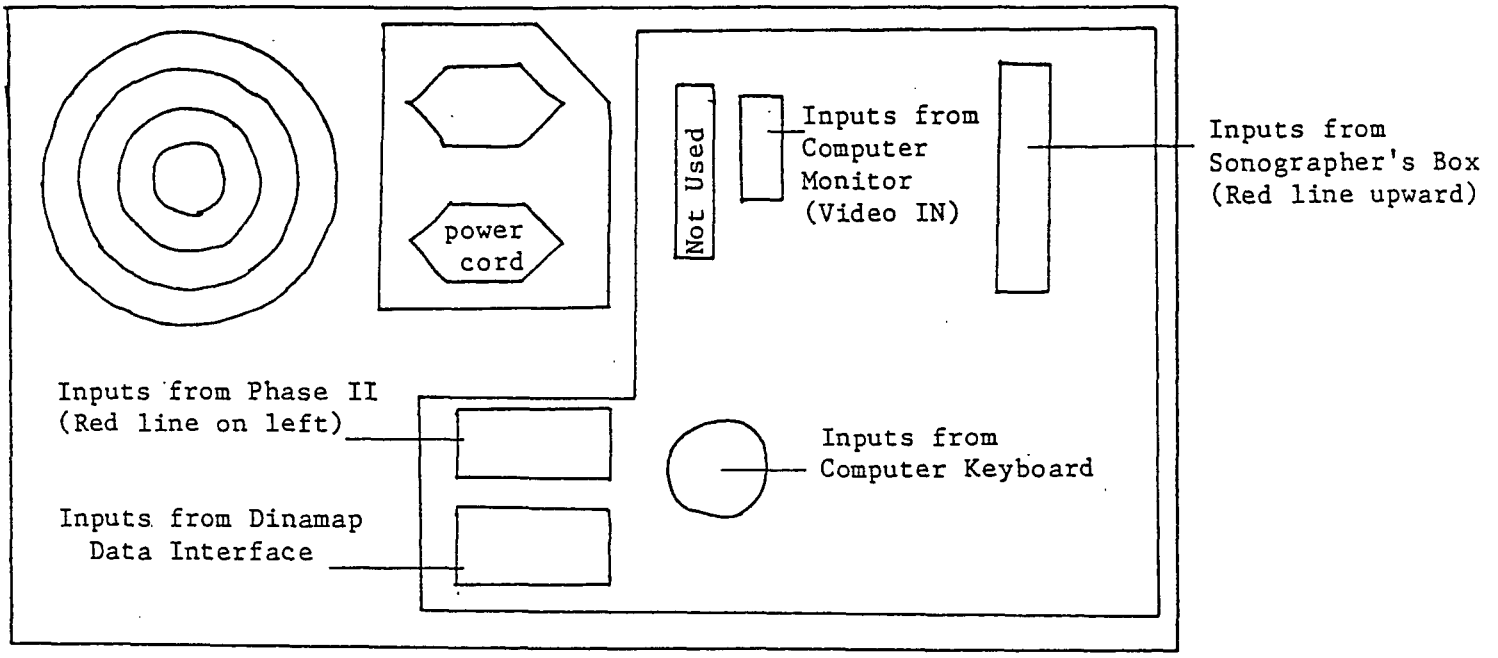

power cord
Not Used
Inputs from Computer Monitor (Video IN)
Inputs from Sonographer's Box (Red line upward)
Inputs from Phase II (Red line on left)
Inputs from Computer Keyboard
Inputs from Dinamap Data Interface

Figure 5. Ultrasound Assessment Equipment: Computer - PC 486

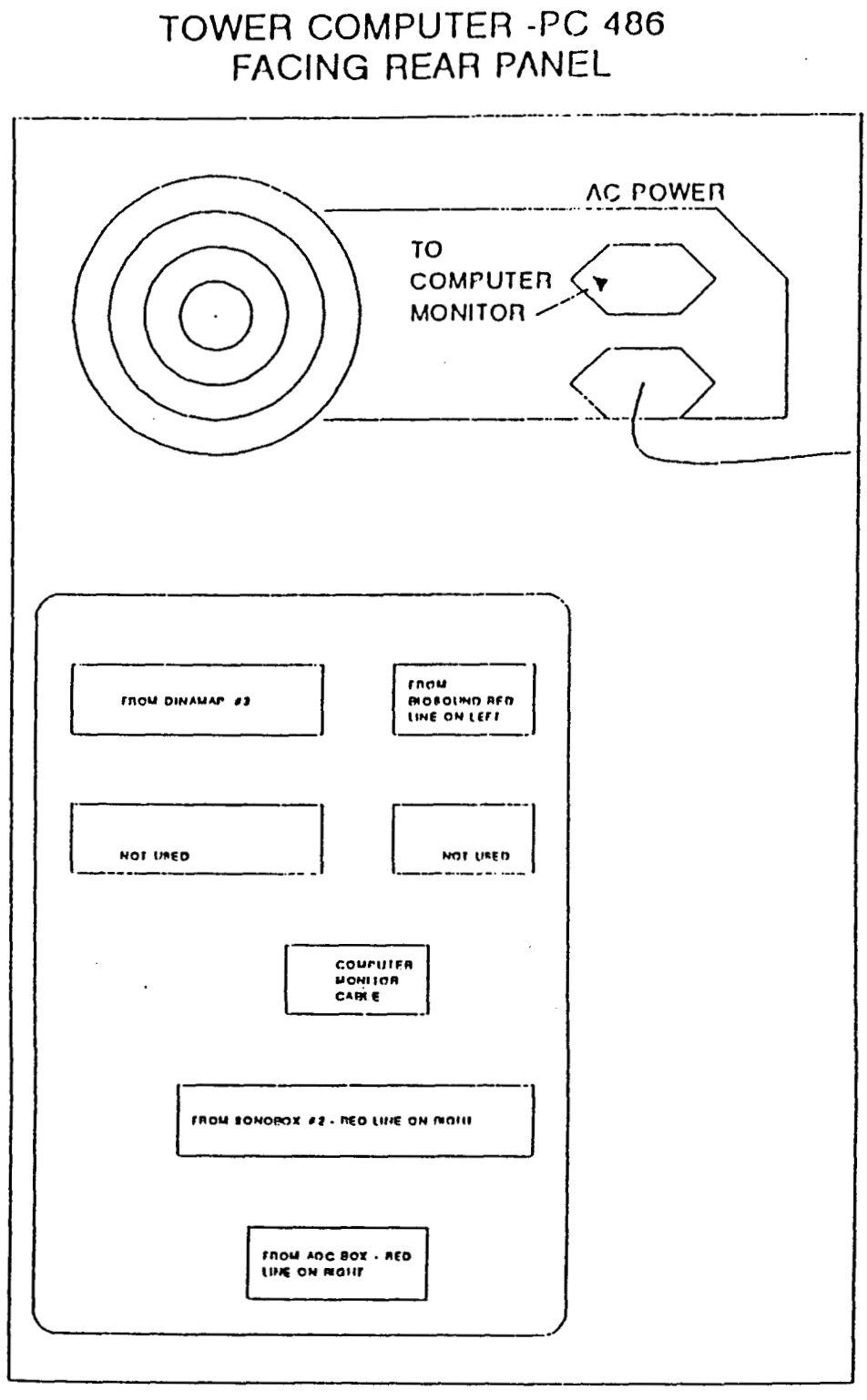


Figure 6. Ultrasound Assessment Equipment: Tower PC 486

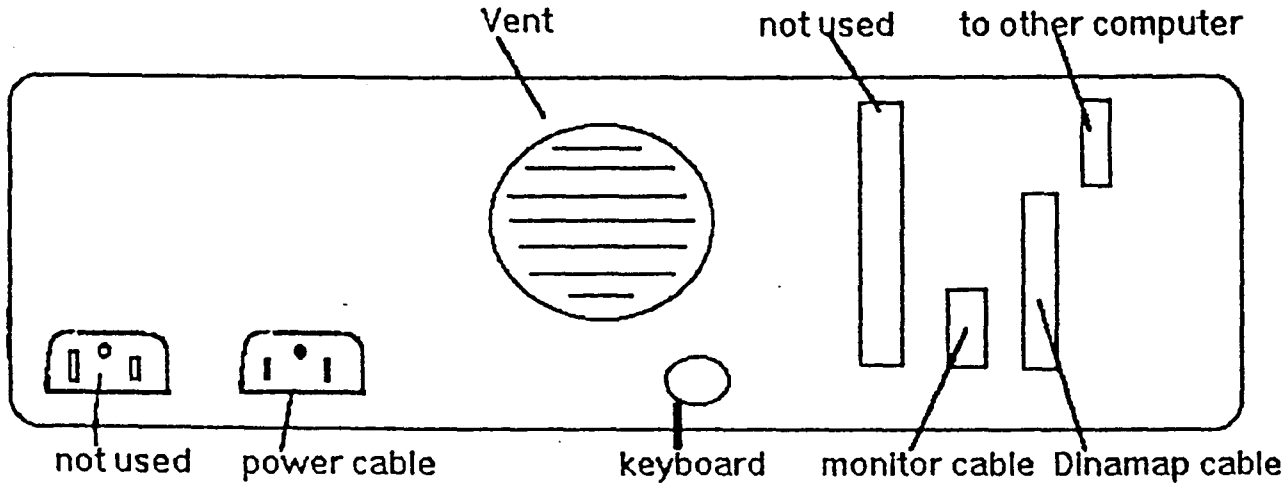


Figure 7. Ultrasound Assessment Equipment: Computer IBM-XT

CABLING CONNECTIONS REFERENCE

VTR LEFT AUDIO OUT	WITH	A/V LEFT AUDIO IN
VTR RIGHT AUDIO OUT	WITH	A/V RIGHT AUDIO IN
VTR RIGHT AUDIO IN	WITH	A/V RIGHT AUDIO OUT
VTR VIDEO OUT	WITH	A/V VIDEO IN
VTR VIDEO IN	WITH	A/V VIDEO OUT
NEC VCR POWER CONNECTION	WITH	POWER SUPPLY NEC VCR
A/V VIDEO PRINTER	WITH	PRINTER V/O IN
NUMBER 8A	WITH	NUMBER 8B
AC LINE	WITH	VIDEO PRINTER

Figure 8. Ultrasound Assessment Equipment: Cabling Connections Reference

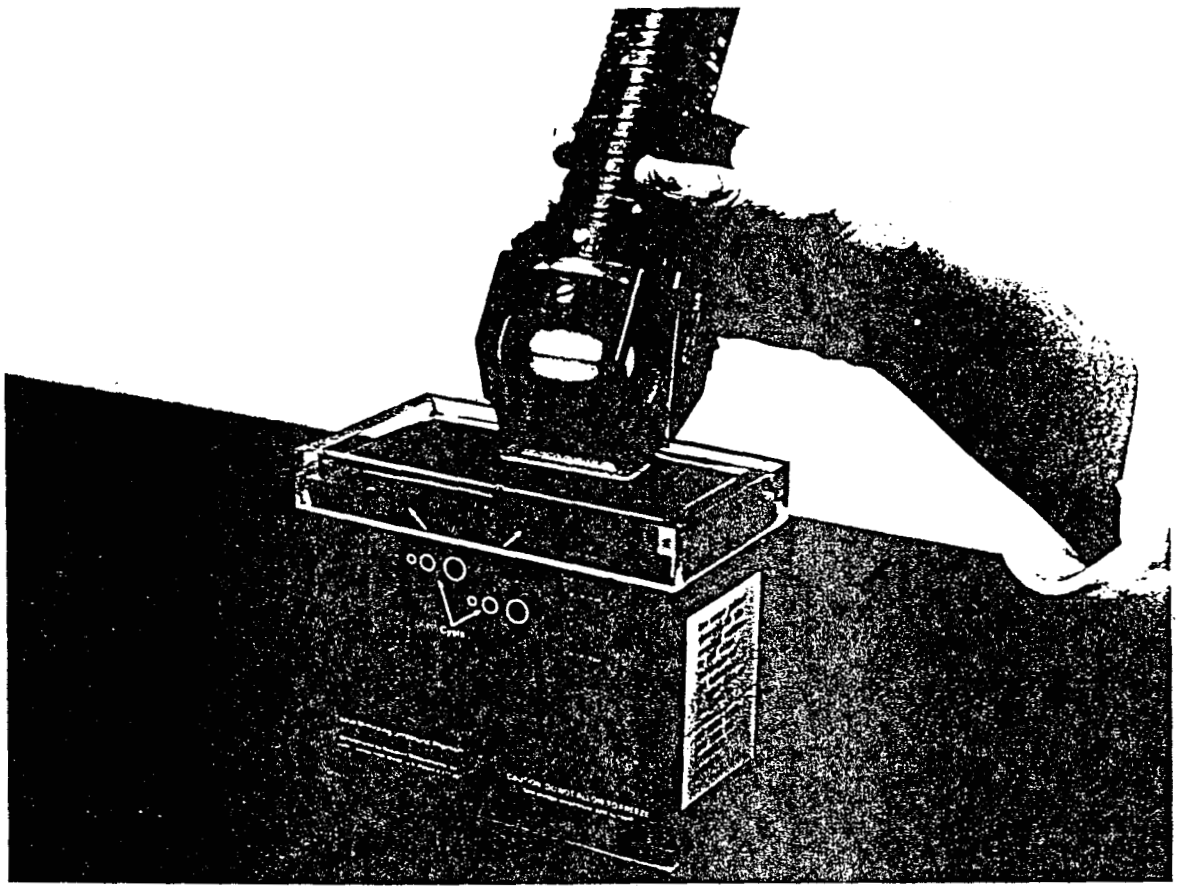


Figure 9. Phantom Placement

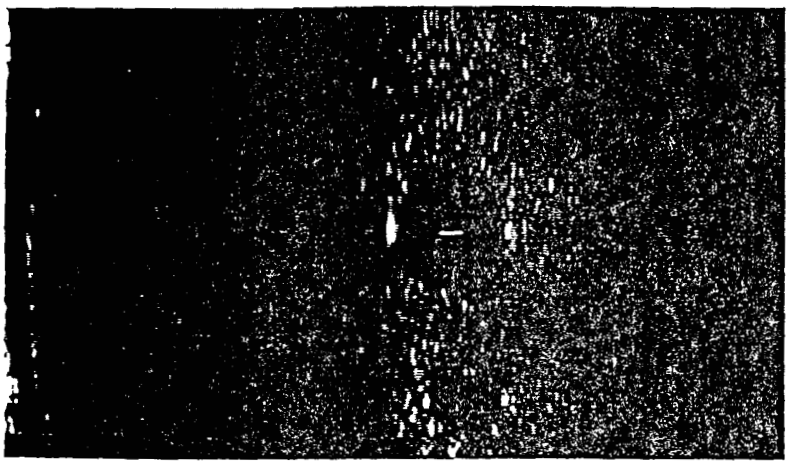


Figure 10. Cross Section or Transverse View of 6 mm Phantom Target

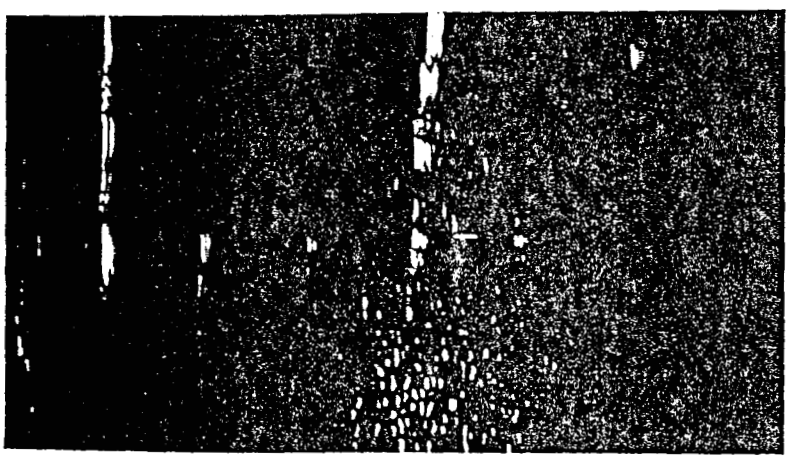


Figure 11. Phantom Filament Images

5. DAILY PRELIMINARIES

5.1 Equipment

The equipment in the ultrasound area is turned on and warmed up for a minimum of 30 minutes before any studies begin. The equipment is to be turned on in the following order:

1. Biosound Phase 2
2. NEC VCR
3. Dinamap
4. Arterial Wall Tracker
5. Strip Chart Recorder
6. Oscilloscope
7. IBM-XT Computer
8. 486 Computer

5.2 Biosound Phase 2 setup

As the unit powers up, the two monitors on the unit will begin to set up their menus. The monitor on the right displays the main menu. The menu displays instructions for the operator to finish the boot-up procedure.

When the "Press any key" message appears on the screen, press the letter "D" on the Phase 2 keyboard and wait for Main Menu to appear on the right monitor of the Phase 2, at the bottom of screen. If any key other than "D" is pressed the unit is put into a "time out" mode. For study purposes a time out mode is not appropriate. Therefore, the operator should press "D". This will put the unit in a continuous mode of operation.

Check the VCR display screen for VCR setting. Check the channel display for setting L. If the "L" is not displayed, press the up and down arrow keys on the VCR keyboard labeled "Channel" until it does appear.

The VCR settings should be as follows:
Panel Settings:

Record Level
L = 5
R = at least 5 or more, adjust to sonographer preference - not to exceed Red level on scale display

Remote Control = ON 1 same as Remote
2 R/C Setting
Tape Remain = T120
Edit = off
Line IN = VIDEO
S-VHS = ON

Keyboard Settings:

TV/CATV = AIR (displayed to the right of counter)
Stereo/ L/R / Normal = L = R
Displayed under audio scale

Select PROBE 1, located on the Biosound Phase 2 keyboard. The probe must warm up for 30 minutes.

The Phase 2 boot-up procedure is now complete.

In order to obtain the highest quality images for this equipment, the Biosound manual directs that the Biosound Phase 2 must be in the LUT LN mode. Check for the "LUT LN" setting on the third line of the right Phase 2 monitor. If the "LUT LN" is not present, press the blue IMAGE PROCESS key and select "LINEAR". This will be displayed in the upper right portion of the screen.

Press the first menu key, located on the Phase 2 keyboard, to make selection for "LUT LN". After acquiring "LUT LN", press the ESCAPE key. (NOTE: Menu keys are the five black keys located at the top of the Phase 2 keyboard.)

Check the image orientation. It must be in standard mode. At the main menu, press the **Image** control option, then press the **TGC** option. Last, press the **Standard** option. Once these steps are completed return to the main menu by pressing **Escape** until the main menu appears.

To enter participant information on the tape menu screen, do the following:

a. Press the 4th menu key to display the Setup menu.
b. Press the first menu key to display Patient menu. Press the first menu key again. Name becomes highlighted. Type in participant's last name, followed by first and middle initials. Press the ESCAPE key or the RETURN key.
c. Press the second menu key for Participant ID information. Type in the field center identification code, followed by the participant's ID number. Example: F123456. Press the ESCAPE key or the RETURN key to return to the Patient menu.
d. When finished, press the ESCAPE key twice to reach the main Menu.

The Doppler cursor can be removed by pressing the green DOP CURSOR key located on the Phase 2 keyboard. This key may be toggled ON or OFF.

The Phase 2 is now set up for scanning.

5.3 Supplies

The supplies to be used for each day are checked. This includes the following:

a. Video cassettes - sVHS cassettes for the NEC PC-VCR
b. 3 1/2" diskette for each for each video cassette
c. Participant ID Labels - Identification labels are applied to the video cassettes and the diskettes used to store participant information.
d. Aquasonic gel
e. Paper wipes
f. 5 1/4" diskette for each video cassette to be used with IBM-XT

6. ARTERIAL SITES AND ANATOMIC STRUCTURES TO BE EXAMINED

Ultrasonic imaging methods are used to obtain a non-invasive quantitative measure of early atherosclerotic disease. The carotid arteries which are the principal suppliers of blood to the brain are a common location for early disease, primarily within or in close proximity to the bifurcation. These arteries, generally located within a few centimeters of the skin surface, are well suited to examination with high resolution ultrasonic imaging methods. The ultrasound examination concentrates around the segment in the right and left carotid artery known as the carotid bifurcation (See Figure 12). Ultrasound examination is attempted at 10 defined sites on the near and far walls within this area. Following a preliminary transverse scan, the sites to be examined are longitudinally visualized in the middle third of the B-mode image screen with the wall boundaries oriented vertically as nearly as possible on the screen.

6.1 Priority for Boundary Visualization

In most instances, it is not possible to simultaneously obtain high quality longitudinal images of both the near and far wall boundaries of the arterial segment being examined in the same image frame. This condition results primarily from the highly specular nature of the ultrasonic reflections from the blood-intima boundaries and the general deviation of the arterial geometry from a cylindrical shape. Consequently, priorities must be placed on which arterial wall boundaries should be visualized with the others being visualized if possible but with potentially lesser quality.

The two boundaries to be visualized first are the media-adventitia boundary on the far wall and the adventitia-media boundary on the near wall. This permits the outer boundaries of the media to be identified and an estimate of the arterial diameter to be measured. The third boundary, the far (deeper) wall blood-intima, then is visualized while maintaining good images of the first two boundaries. This permits a measurement of the far wall intimal-medial thickness. Fourth, if possible without losing this third boundary, the intima-blood boundary on the near (shallower) wall is visualized. An image of the common carotid artery in which all four boundaries are visualized is shown in Figure 13. This sequence of priorities is used when imaging any segment of the carotid arteries with the exception of special views at the bifurcation and the internal carotid. These are discussed in Section 6.2.

6.2 The Carotid Arteries

6.2.1 Anatomical References

The arterial segments defined for ultrasonic examination are referenced to certain anatomical landmarks which are normally identifiable within the carotid system. One is the tip of the flow divider which defines the position along the vessel where the internal carotid artery and external carotid artery begin. A second, but less clearly delineated, is the location where the common carotid artery begins to widen into the carotid bifurcation. These landmarks are illustrated in Figure 12. In order to image defined segments referenced to these landmarks, longitudinal images are required. During each image sequence the cursor on the Biosound image screen is placed at the vertical level of the appropriate landmark for use in the reading of the B-mode images at the Ultrasound Reading Center.

6.2.2 Optimal Interrogation Angle

The optimal ultrasonic interrogation angle which permits clear identification of the anatomical references on the B-mode images depends upon specific anatomical features of the participant. This dependence of interrogation angle on the individual participant requires that great care be given during the preliminary examination to identify this angle. It depends upon both the ultrasound transducer position and the orientation of the head of the participant.

If the proximal segments of the internal and external carotid arteries lie in a common plane, it should be possible to interrogate the bifurcation from an angle which provides an image characterized by a "Y" appearance. This is illustrated in Figure 14. From this angle, the location of the two anatomical references, the tip of the flow divider and the initial common carotid widening into the bifurcation, can be seen. In some individuals, it is often difficult to sharply define the origin of the bifurcation if a pronounced widening does not occur, but it is most likely to be visible from this angle.

If the proximal segments of the internal and external carotid arteries do not lie in a common plane, it may be impossible for the sonographer to obtain the characteristic "Y" appearance at the bifurcation. Either one or the other of the branches can be imaged at a given interrogation angle but not both. In many cases, repositioning of the head of the participant (see Sections 8.1. and 8.2) may permit the two arteries to more closely approach a common plane. Often careful attention to this position and small participant head angle changes will permit the "Y" to be visualized. A preliminary transverse scan as described in Section 8.1.3 permits the optimal interrogation angle to be closely approximated even in the more difficult anatomical configurations.

6.2.3 The Common Carotid Artery

Images of the common carotid artery are obtained at the optimal interrogation angle. They are referenced to the origin of the bifurcation where the common carotid begins to widen. The segment located 10 mm proximal to this landmark is the focus of attention. Both the near wall and far wall interfaces are attempted in this view.

6.2.4 The Carotid Bifurcation

The segment of the carotid bifurcation extending 10 mm proximal to the tip of the flow divider is imaged at the optimal angle. In some participants this may extend into the common carotid. The sonographer must place the cursor at the level of the tip of the flow divider. Images are then acquired at this interrogation angle taking great care to use the priority sequence of boundary visualization described in Section 6.1.

6.2.5 The Internal Carotid Artery

The segment of the internal carotid artery far wall extending 10 mm distal from the tip of the flow divider is now imaged at the optimal angle. Images are acquired of this segment once again marking the tip of the flow divider as the anatomical landmark. It is important to carefully distinguish between the internal and external carotid arteries using two criteria: 1. normally the internal has a significantly larger diameter than the external; 2. the blood flow velocity pattern in the two vessels as determined with Doppler ultrasound

is distinctly different. Used together, these two considerations permit the internal carotid artery to be identified with a high degree of confidence.

During the preliminary scanning procedure it is necessary to distinguish clearly between internal and external carotid arteries. Although tributaries originating from the external carotid artery may occasionally be viewed with B-mode ultrasound to help in this differentiation, Doppler ultrasound in most cases is more efficient and specific for this separation. The method and criteria for this identification are as follows:

A B-mode image is obtained of the carotid bifurcation where the common carotid artery divides. In some instances the best anatomical angle will show the flow divider as well as the proximal internal and external carotid arteries. In the remaining cases the flow divider and only one vessel can be seen from a single angle. In those instances the other artery can be visualized by gently rocking the ultrasound probe back and forth in angle or position or both. Doppler is used to differentiate internal and external carotid arteries in these instances. To obtain a Doppler sample of each artery, the Doppler sample volume is placed into the branch farthest from skin surface. The sonographer observes the tracing on the TV monitor and listens to the Doppler signal. If the ultrasound probe is in the internal carotid artery, the flow pattern will be that of a low-resistance bed. This signal has a rapid upstroke and a quasi-steady flow through systole and diastole. The flow continues throughout the cardiac cycle and begins to increase again at the next systole.

The flow pattern is graphically displayed near the zero baseline. Flow directed toward the head and away from the heart throughout the cycle is represented as a tracing above the baseline in Figure 15. If the Doppler signal does not correspond to the expected pattern, the cursor is placed within the other branch of the common carotid artery. The external carotid artery is usually nearer the skin surface when viewed from an anterior angle and is a high-resistance vessel. The characteristics of the Doppler signal in this vessel are a forward flow with a sharp upstroke and sometimes a reversal of the flow at diastole (multiphasic). The hallmark of a high-resistance artery is cessation of flow before the onset of the next systole as defined in Figure 16.

Abnormal flow is demonstrated by turbulence within the lumen and disruption of normal flow. This is identified in the Doppler signal by broadening the Doppler spectrum. Severe narrowing of the artery lumen is identified by an increase in the expected peak systolic frequency. If occlusion is present there will be no Doppler signal, in which case the external and internal carotid arteries can be defined by the external being more anterior to the internal anatomically. If flow is sampled from the common carotid artery, there will be a rapid systolic up-stroke with small reversal of flow and a quasi-steady flow throughout diastole. This is a combination of internal and external carotid flow patterns, as shown in Figure 17. Because of the more varied positioning and geometry of the internal carotid, the sequence of priorities to be used when imaging this segment is modified from that used in the common and bifurcation. The two far wall boundaries should receive highest priority, the near wall adventitia-media interface next priority and finally the near wall intima-blood boundary.

6.2.6 Independent Views of the Far and Near Bifurcation Walls

6.2.6.1 Far wall

After imaging the far wall of the internal, the carotid bifurcation at the optimal angle is imaged again. The ultrasound transducer is tilted along the arterial axis in such a manner that the far wall of the bifurcation becomes vertical in the center of the display screen. The quality of the near wall echoes will deteriorate. At this time, small changes in transducer angle are made to image the far wall blood-intima and media-adventitia interfaces. After the far wall image is obtained, the transducer is rotated back to obtain the carotid bifurcation optimal angle image again.

6.2.6.2 Near wall

The transducer is rotated along the axis of the artery so that the near wall of the bifurcation is now oriented vertically in the center of the display screen. The quality of the far wall echoes will deteriorate. Small changes in transducer angle are made to image the near wall adventitia-media and intima-blood interfaces.

6.3 Cursor Placement by Site and Side

6.3.1 Ultrasound Monitor

Horizontal parallel lines should be marked in black on the image screen of the ultrasound B-mode image monitor. These lines serve to delimit the optimal imaging region which is this middle portion of the image area. These lines are referred to as the upper and lower imaging lines. The two horizontal lines shown on Figure 18 are located where the black lines should be marked on the image screen. These lines are to be positioned 3/4 inch inside the top and bottom portion of the active B-mode imaging area. The crosshair (+) is placed at the level of one of these lines to mark the location of the anatomical landmark for the specific site being imaged. The placement of the crosshair is illustrated for all sites in Figure 19.

6.3.2 Common Carotid Crosshair Placement

The common carotid artery image is oriented so that the arterial walls appear vertically on the monitor screen. The ultrasound transducer is moved so that the upper imaging line marked on the Biosound screen passes through the origin of the bifurcation on both near and far arterial walls. The crosshair is placed on the upper imaging line, approximately in the center of the lumen. The optimum ultrasound image appears between the upper and lower imaging lines (described in section 6.3.1). For the left common carotid artery, the ultrasound transducer is moved so that the lower imaging line passes through the origin of the bifurcation on both near and far arterial walls. The crosshair is placed on the lower imaging line, approximately in the center of the lumen. The optimum ultrasound image appears between the lower and upper imaging lines.

6.3.3 Bifurcation Area Crosshair Placement

The landmark for all images in the bifurcation area is the tip of the flow divider. In some views, the tip of the flow divider may disappear, but the crosshair should indicate its location on the monitor screen.

For the right side, the tip of the flow divider is placed on the upper imaging line. The crosshair is placed on the upper imaging line at the tip of the flow divider. The crosshair is placed within the lumen, to assure that it will be well clear of all measurement areas. The optimum ultrasound image appears between the upper and lower imaging lines.

In the two views of the bifurcation when only the right far wall or near wall is imaged, the tip of the flow divider is placed on the upper imaging line. The crosshair is also placed on the upper imaging line. The ultrasound transducer is manipulated until the far or near wall image is optimized. The crosshair is then moved to a position along the upper imaging line near the wall interfaces being imaged. The crosshair should not interfere with the wall interfaces being imaged, but remain in the lumen area.

For the left side, the tip of the flow divider is placed on the lower imaging line. The crosshair is placed at the tip of the flow divider on the lower imaging line. The optimum ultrasound image appears between the lower and the upper imaging lines.

In the two views of the bifurcation, when only the left far wall or near wall is imaged, the tip of the flow divider is placed on the lower imaging line. The ultrasound transducer is manipulated until the far or near wall image is optimized. The crosshair is then moved to a position along the lower imaging line near the wall interfaces being imaged. The crosshair should not interfere with the wall interfaces being imaged, but should remain in the lumen area.

6.3.4 Internal Carotid Crosshair Placement

The landmark for the internal carotid artery is the tip of the flow divider. Primarily, the far wall of the internal carotid is imaged.

For the right side, the tip of the flow divider is placed on the lower imaging line. The crosshair is placed on the lower imaging line, approximately in the center of the lumen. The optimum ultrasound image appears between the lower and upper imaging lines.

For the left side, the tip of the flow divider is placed on the upper imaging line. The crosshair is placed on the upper imaging line, approximately in the center of the lumen. The optimum ultrasound image appears between the upper and lower imaging lines.

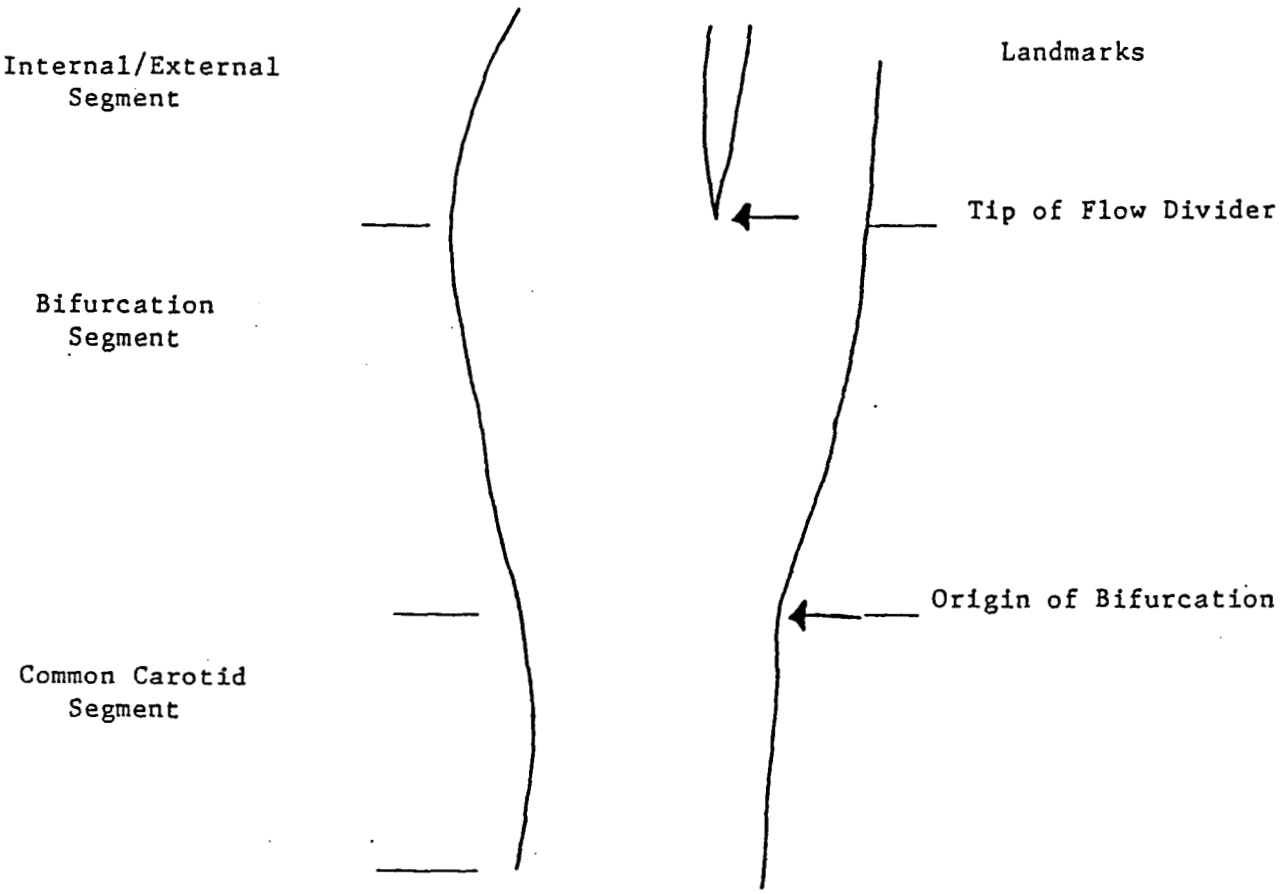
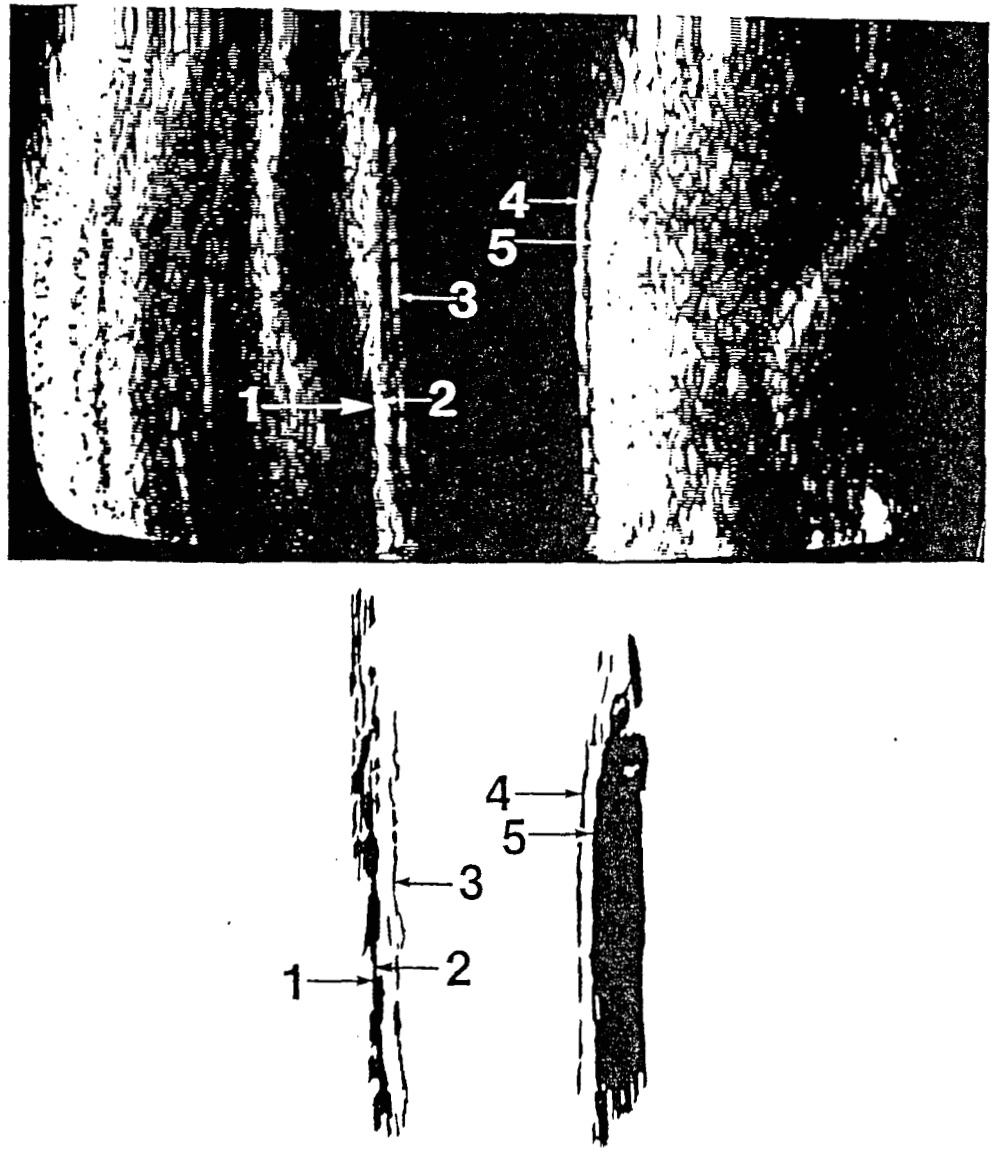


Figure 12. Schematic of Carotid Artery Segments Interrogated

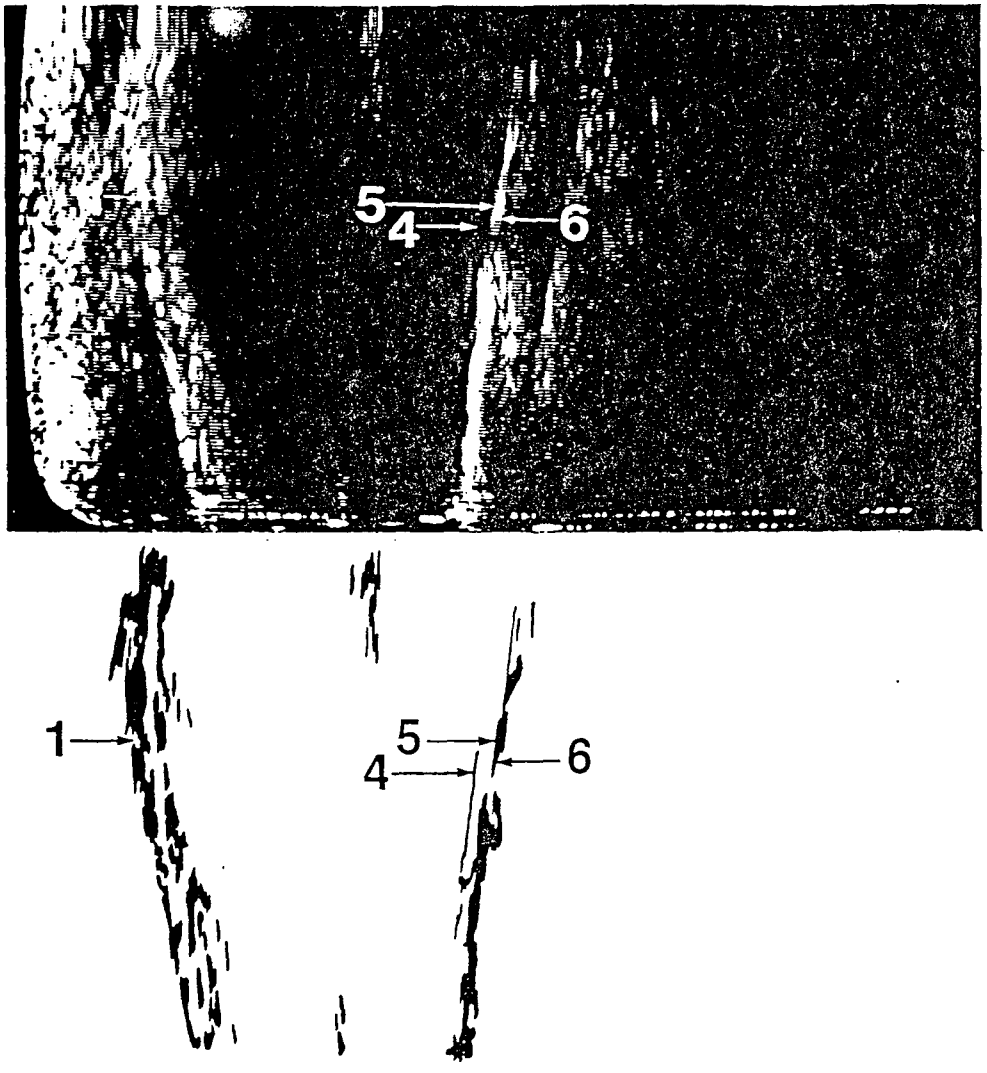
Right Common Carotid Artery



1. Periadeventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 13 Common Carotid Artery (all four boundaries visualized)

Right Carotid Bifurcation



1. Periadeventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 14. The Bifurcation

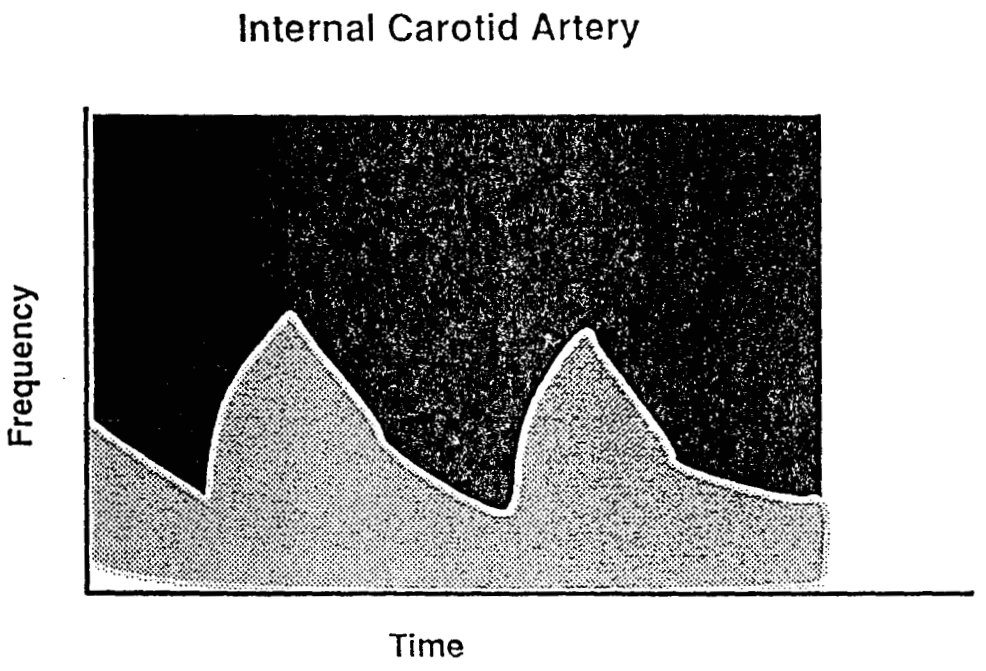


Figure 15. Doppler Tracing: Internal Carotid Artery

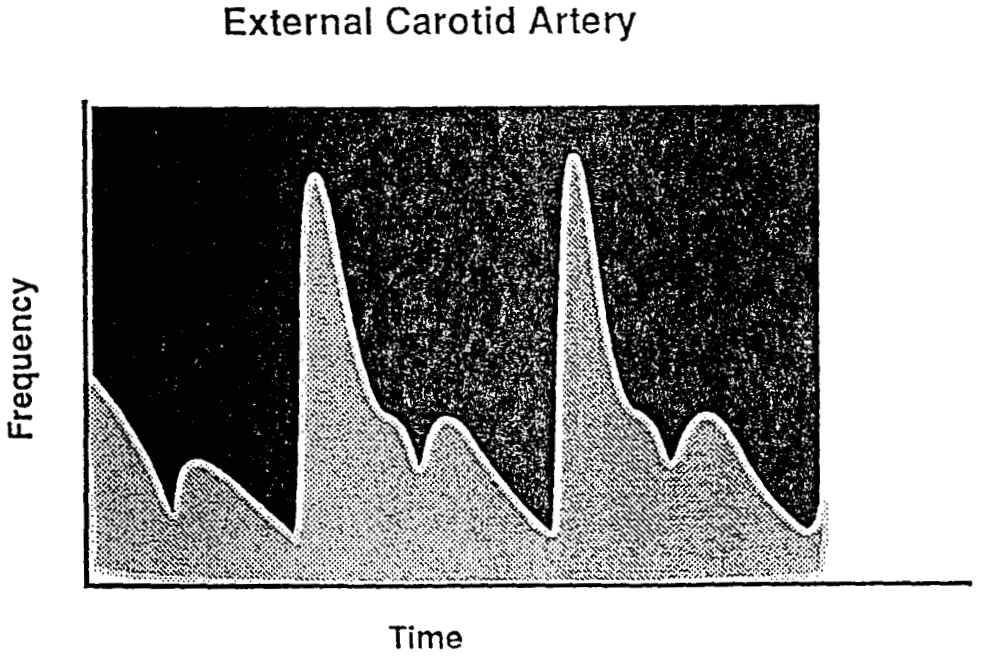


Figure 16. Doppler Tracing: External Carotid Artery

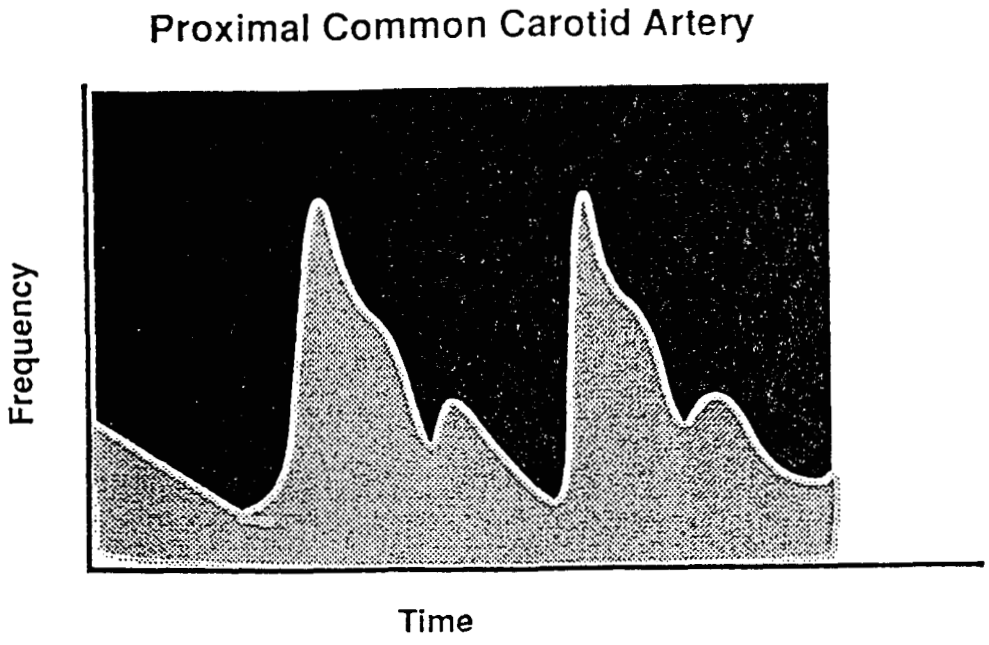


Figure 17. Doppler tracing: Combination of Internal and External Carotid Flow Patterns

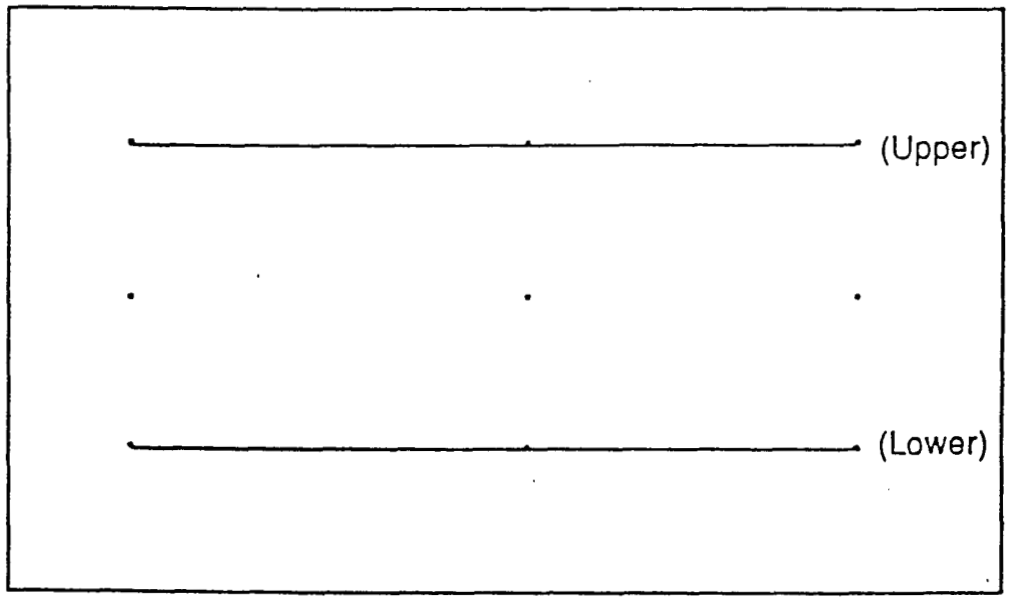


Figure 18. Biosound Screen Calibration Procedure

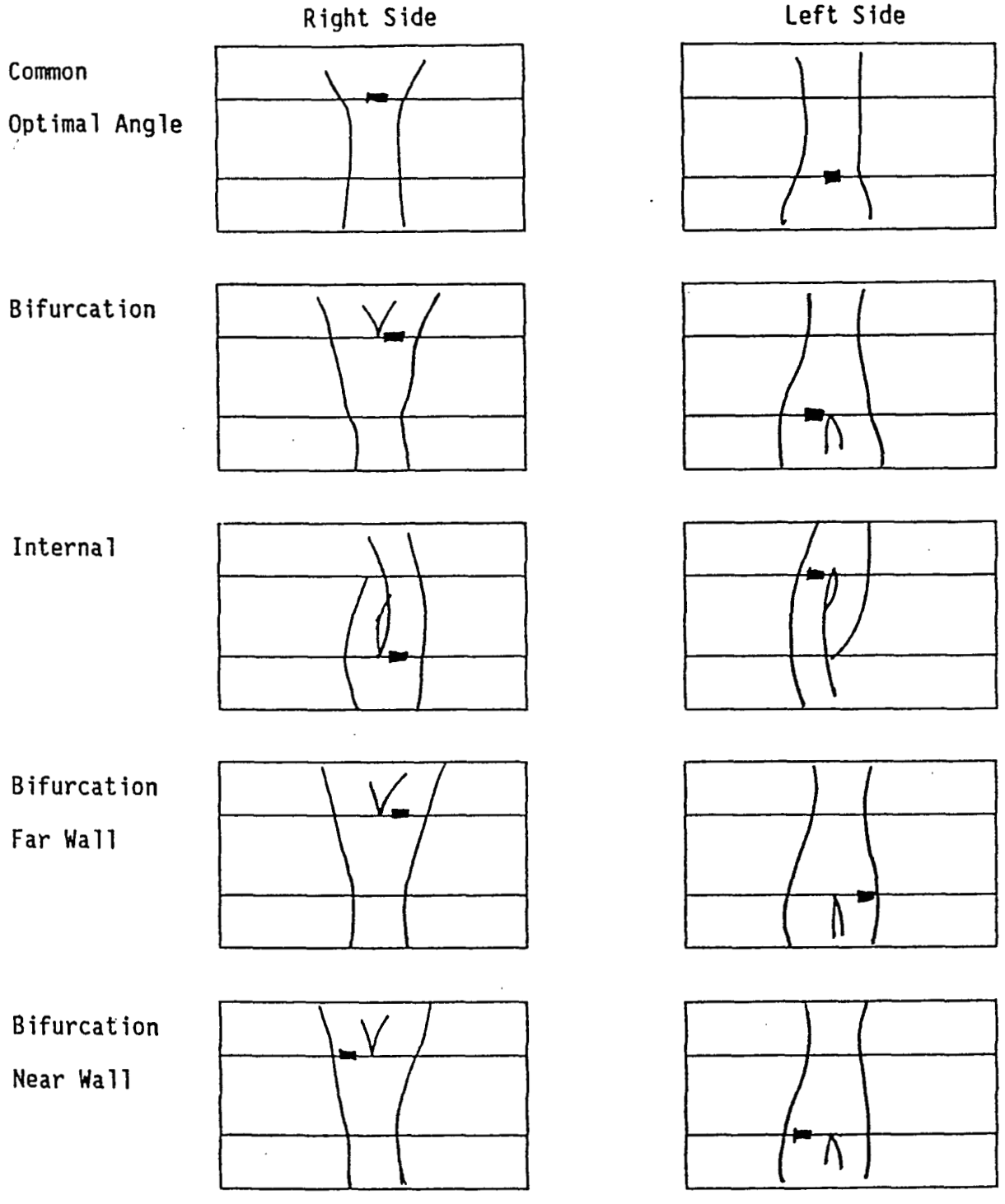


Figure 19. Image As Seen On Biosound Monitor: Proper Cursor Placement

7. PARTICIPANT PRELIMINARIES

The participant will have been asked to refrain from smoking, vigorous exercise, and drinking coffee, tea and soft drinks containing caffeine during the night preceding and the day of the ultrasound examination, since these may alter heart rate and/or blood pressure.

7.1 Participant Orientation to Ultrasound Examination

The participant is positioned on the exmination talbe in a supine position. The sonographer describes in general terms the examination to be done. A suggested statement follows:

"Ultrasound is a new painless and low-risk method to examine arteries using sound waves which you cannot hear but which are able to 'see' arteries under your skin. Before the ultrasound exam begins, a thin gel will be applied to the skin, and an instrument will be placed on it. This procedure will be used to look at the arteries on both sides of your neck. During the examination, you will hear the noise and feel the vibrations of a small motor that is located within the instrument. Occasionally you will also hear the amplified sound of blood flowing through your arteries. The equipment will also record my voice as I name the parts of the arteries I scan. The complete ultrasound examination should be completed within forty-five minutes. Since talking or swallowing can cause the arteries to move out of focus and cause this procedure to take longer, your cooperation would be appreciated."

During this discussion, the sonographer should remember that the examination to be done <u>is not</u> diagnostic in nature, and that all questions asked by the participant that relate to the presence or absence of arterial disease should be referred to the medical director of the Field Center or to his on-site representative. Information to be given to the participant or his/her physician is described in Manual 2.

7.2 Participant Apparel

The ultrasound component of this examination requires easy access to the skin overlying arteries in the neck. Participants wear loose fitting apparel provided by each field center. Jewelry present on the head and neck, including gold chains, necklaces and earrings, is removed prior to scanning.

7.3 Study Preliminaries

7.3.1 IBM-XT Computer

The order in which the blood pressure equipment is turned on is critical to the successful functioning of the computer system. The Dinamap is first turned on. **It is essential that the Dinamap be in Manual Mode at all times.** The IBM XT computer is then turned on.

After receiving replies to prompts for date and time correction, the IBM XT computer displays a C:\> prompt. The sonographer then types the command: **GETBP** on the IBM XT keyboard and presses the **ENTER** key. The computer prompts the sonographer for the participant ID number by displaying the following:

ENTER PARTICIPANT ID :

The sonographer then enters the field center letter, followed by the participant ID number and presses ENTER. If a file for that participant already exists, the monitor will display the message:

X12345 ALREADY EXISTS. DO YOU WISH TO OVERWRITE

The computer program is not designed to save more than one file on any participant. If the response entered by the sonographer is "n", the program automatically ends and returns the computer to the DOS prompt. If the response entered is "y" or any other key except "n", the existing file will be overwritten by the file being created during this study.

After the participant ID number has been accepted by both sonographer and computer, the IBM XT computer monitor will display the message:

Ready to take blood pressure

7.3.2 486 Computer

To initiate the ultrasound study flow program, type **aricscan** at the **C:\>** prompt and press ENTER. The date appears. If it is correct, press the ENTER key. If the date is incorrect, type the correct date and press the ENTER key. After pressing the ENTER key, the time appears. Verify or correct it as instructed above and press the ENTER key. After pressing the ENTER key, ARIC STUDY appears, very quickly followed by the VERSION screen. Press the ENTER key. The computer screen will read "**MOUNT TAPE AND MOUNT DISK B DRIVE. ENTER WHEN READY.**"

The ENTER key is pressed after completing each field on the screen. When the sonographer enters information on the screen, he/she may move back to make corrections by using the arrow keys on the keyboard.

7.4 Preliminary Questionnaire

The operator completes the questionnaire as follows. The 486 computer screen will read:

PUT TAPE IN THE PHASE 2 VCR and PUT (3 1/2") DISK IN DRIVE B.

Follow the instructions, placing a sVHS videotape cassette in the VCR, and a previously formatted 3 1/2" diskette. Press the ENTER key.

After pressing the ENTER key, a WAIT message appears while the Phase 2 is setting up to record on the tape.

Wait until the Demographic screen appears. One by one, the field requiring information to be supplied by the sonographer will be highlighted in yellow. For example, when the Patient ID is yellow, the sonographer would then type in the participant's ID number, followed by the ENTER key. Note that the field center (first) character is inserted automatically. If the ID's do not match, the sonographer should determine which computer has the wrong ID. Then, exit the program on that computer and re-initiate the program, and enter the ID correctly.

Type the Visit Code, using two digits, and press the ENTER key. Type the Sonographer ID, using three digits, and press the ENTER key. Verify the Cassette ID and press the ENTER key. The Cassette ID is automatically assigned by the computer program. Type participant's initials, last name, gender, race and date of birth, pressing the ENTER key after each entry.

When all fields have been filled in **EVERYTHING CORRECT?** appears on the lower portion of the screen. Answer **N** or **Y**. **N** signifies that an error was made in the demographic entries. **Y** signifies that everything is correct. If the choice made is **Y**, a wait screen appears while the VCR sets up to begin recording. (Do not press the ENTER key while the WAIT screen is visible.)

If the choice is **N**, the demographics screen appears again, and incorrect entries are re-typed. (See above). After the last entry, VERIFY appears again. Type **Y** if all is correct: if not, type **N** and loop through this process once more.

Information from this questionnaire is entered into the field center computer. This information will be sent to the reading center on a diskette under the participant's .DEM file.

7.5 Blood Pressure

7.5.1 Applying the Blood Pressure Cuff to the Ankle

If the date is an even number, place the cuff on the left ankle; if the date is an odd number, place the cuff on the right ankle. Apply the ankle blood pressure cuff to the lower extremity selected. (Socks or stocking have been removed, or moved below the ankle to keep the participant's foot and/or toes warm if the room is cool). Where practical, use the same cuff for the ankle as for seated blood pressure. This information is found in the participant's chart. If the participant's ankle is very large and/or strongly tapered, a larger cuff may be necessary.

While ankle blood pressures are obtained, the participant should be in a supine position without any pillows or support under the legs, unless this causes discomfort. In most cases the participant will be comfortable in that position for the short time needed to take the ankle blood pressure. If a participant feels that a pillow is necessary, provide one and indicate on the log sheet that a pillow was used during ankle blood pressure.

Proper application of the appropriate cuff above the ankle of the selected leg is shown in Figure 20 or 21. Lay the cuff flat on the table (the surface marked "side to the patient" face up) with the ankle centered on the cuff. For the moment, disregard the "over the artery" marker. The lower edge of the cuff, from which the tubes extend, should be approximately 2 to 2 1/2 inches above the medial malleolus. Following the contour of the lower leg, wrap the end of the cuff with the Velcro fastener over the ankle, as shown in Figure 20 or 21. Note that depending on the degree of tapering in this area, the cuff corner will be offset from parallel toward the knee.

Holding the cuff from sliding, wrap the other end over the ankle as shown in step III in Figure 20 or 21, again following the contour of the ankle, and secure the Velcro fastener. Check to be sure that the corners of the cuff extending above the upper edge of the cuff are about equal. If one end extends more than the other, loosen the Velcro and adjust the wrap.

Next, locate the "over the artery" marker of the cuff, and rotate the cuff so that this line is directly over the posterior tibial artery. The cuff may be rotated more easily by sliding it toward the malleolus, and after alignment, the cuff can be made snug by pulling it up toward the calf. The cuff should conform closely to the shape of the ankle, with the lower edge 1 to 2 1/2 inches above the malleolus.

The posterior tibial artery is usually palpated as it courses posteriorly to the medial malleolus. Even if the posterior tibial pulse is not palpable, the posterior tibial artery is used as the location for the marker line on the cuff for the "over the artery position". Any kinks in the tubing are removed, and tension on the tubing on the participant's leg is relieved. If needed, masking tape or hospital clips are applied at this time to anchor the tubing to the ultrasound table to maintain this position.

Explain the blood pressure measurement procedure as the cuff is put into place. Be sure to explain that repeated blood pressure measurements will be obtained automatically. Advise the participant that the <u>first</u> inflation is always somewhat uncomfortable due to lack of "individualized" adjustment by the machine to that particular person's blood pressure. Subsequent readings require a lower pressure and will cause less discomfort.

If an adequate systolic blood pressure measurement is not obtained at the ankle, verify that the cuff has been wrapped appropriately and has not slipped. If upon inflation the cuff rolls down toward the foot, the cuff should be reapplied more snugly. If the cuff unwraps upon inflation, a larger cuff may be substituted. If a cuff is rewrapped or changed, an additional manually-triggered BP is taken.
Observe the participant for a tendency to "stretch" the calf or wiggle the foot during the blood pressure reading. If it occurs, discuss the effect of this action with the participant before the ultrasound scan is started, stressing the need for the leg and arm to be kept still during the blood pressure readings. Discomfort during the blood pressure measurement may indicate that the ankle cuff has been applied too tight, <u>not</u> applied smoothly, or that it is too narrow.

Once the ankle blood pressure is completed the cuff is removed from the ankle. The participant's sock and/or blanket is replaced to make the participant comfortable as the blood pressure procedures move to the arm.

7.5.2 Applying the Blood Pressure Cuff to the Arm

Proper size of the cuff is essential for accurate blood pressure measurement. Field Centers have four standardized cuffs available - small adult, adult, large adult, and thigh cuff. The same standardized cuff sizes are used for sitting blood pressure and for the measurement of postural changes in Ultrasound blood pressure.

Use the cuff size used for the sitting blood pressure measurements, (recorded on the Itinerary Form) for selecting the size of the Dinamap cuff for the upper extremity. The standard cuffs provided are by the Baum Company for the sitting blood pressure, and by Dinamap for the blood pressure measurements at the Ultrasound work station.

Once the participant is given instructions and explanations, and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely.

1. If the participant indicates that there is a medical or post-surgical reason for not having the blood pressure measured on the right arm, or if the right arm is missing, proceed with the left arm. Indicate on the Itinerary Form and on a Note Log that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, the sonographer should consult with their immediate supervisor.

2. If the arm circumference has not been measured at the Sitting Blood Pressure station, have the participant stand facing away from the observer with the right arm bent 90 degrees at the elbow, hand on midsection. Locate the tip of the acromion, (at the top outer edge of the shoulder blade) and measure the length of the upper arm from acromion to tip of elbow using a centimeter tape measure. Mark the midway point of the arm and then have the participant relax the arm at the side. Wrap the tape around the arm over the midpoint mark, making sure that the tape is level. Measure the arm circumference to the nearest 1/2 centimeter and record. See Table 1. below:

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the ARIC Study arm size is measured, and the cuff size is selected as follows:

Table 1. Determination of cuff size based on arm circumference

Cuff Size	Arm Circumference
Small Adult	< 24 cm
Adult	24 to 32 cm
Large Adult	33 to 41 cm
Thigh	> 41 cm

The ultrasound part of the exam begins.

Before activating the next phase of the study, take a minute to instruct the participant on the "no conversation" rule. Also, remind the participant to "hold questions" about exam results until after the last portion of the ultrasound station exam is completed, since it is important that all participants be "treated the same way".

7.5.3 Blood Pressure Examination

Instructions to position the cuff and to take manual ankle pressure will appear on the ultrasound computer monitor. The computer monitors will display the following messages:

486 DELL/CSA Monitor	IBM Monitor
MANUAL ANKLE blood pressure **Press M on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on DELL/CSA keyboard**	**Ready to take blood pressure**

Press M on the IBM keyboard.

If an adequate systolic blood pressure measurement is not obtained at the ankle, the sonographer verifies that the cuff has been wrapped appropriately and has not slipped. If upon inflation the cuff rolls down toward the foot, the cuff should be reapplied more snugly. If the cuff unwraps upon inflation, a larger cuff may be substituted. If a cuff is rewrapped or changed, an additional manually-triggered BP is taken.

486 Computer Monitor	IBM Computer Monitor
MANUAL ANKLE blood pressure Press M on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap

After the manual blood pressure is taken the screens will read:

486 Computer Monitor	IBM Computer Monitor
MANUAL ANKLE blood pressure Press M on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure

Press Y and ENTER on the 486 computer keyboard.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ANKLE Press A on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure

Press A and ENTER on the IBM keyboard.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ANKLE **Press A on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on DELL/CSA keyboard**	Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure **Received command to take ankle bp**

After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ANKLE **Press A on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on DELL/CSA keyboard**	Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure Received command to take ankle bp **A 12:33.50 BBA13053400130533093082132068**

After the ankle blood pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ANKLE **Press A on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on DELL/CSA keyboard**	Received command to take ankle bp A 12:33.50 BBA13053400130533093082132068 **Ready to take blood pressure**

The cuff is removed from the ankle. See Section 7.5.2 for **arm cuff** application.

Press Y and ENTER on the 486 computer keyboard. The computer monitors will then read:

486 Computer Monitor	IBM Computer Monitor
MANUAL ARM Press M on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Received command to take ankle bp A 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure

Press M on the IBM keyboard. Shortly after M is pressed on the IBM keyboard, the IBM computer will append the following message on the screen:

486 Computer Monitor	IBM Computer Monitor
MANUAL ARM Press M on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Received command to take ankle bp A 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap

After the manual blood pressure is taken, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
MANUAL ARM Press M on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure

Press Y and ENTER 486 computer keyboard.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM Press B on the IBM keyboard. To CONTINUE press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure

Press B and ENTER on the IBM keyboard.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM Press B on the IBM keyboard. To CONTINUE press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure Received command to take arm bp

Press Y and ENTER on the 486 computer keyboard to continue.

After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM Press B on the IBM keyboard. To CONTINUE press Y and ENTER on DELL/CSA keyboard	Received command to take manual bp This will calibrate the dinamap Ready to take blood pressure Received command to take arm bp B 12:33.50 BBA13053400130533093082132068

After the arm blood pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	This will calibrate the dinamap
Press B on the IBM keyboard.	Ready to take blood pressure
To CONTINUE	Received command to take arm bp
press Y and ENTER on DELL/CSA keyboard	B 12:33.50 BBA13053400130533093082132068
	Ready to take blood pressure

Arm blood pressures will be taken intermittently during ultrasound. The CSA/Dell will prompt the sonographer for BP initiation.

At the end of the study, the program is automatically exited. The program creates a file containing the recorded blood pressures, which is placed in the "studies" directory. The file is named with the participant ID as the file name and bp as its extension, i.e., X******.bp, where X represents the field center code, and the asterisks represent the participant ID number.

At the conclusion of the examination, the sonographer copies the blood pressures files onto a floppy diskette along with the other participant files, and sends the diskette along with the videotape to the Ultrasound Reading Center.

7.6 Preparation for Ultrasound Examination

The subject is in a supine position with his/her legs resting comfortably on a pillow. The participant's position should allow head rotation to either side. The sonographer is seated at the end of the exam table that is nearer the participant's head. The top of the participant's head is about one to three inches from the end of the exam table, so as to afford easy access to the sonographer of the areas of the neck to be scanned.

When the 486 computer screen reads:

Insert Tape and Diskette and Press ENTER when ready

Insert tape and diskette, and press ENTER. The 486 computer screen will read:

Press Record

Press RECORD on Sonographer Box. The NEC PC-VCR is automatically placed in the RECORD mode by the computer. A red circle on the VCR front panel indicates that this VCR is recording.

A study code flow screen will appear on the 486 monitor. The text will be color coded as follows:

- Yellow highlight indicates that a code is to be scanned.
- Pink highlight indicates that a code is to be scanned next.

- Green highlight indicates that a code has been scanned.

The 486 computer screen will now display the first scanning screen, which looks like this:

486 Computer Monitor	IBM Computer Monitor
*** PRESS RECORD TO START ***	Ready to take blood pressure
012 Start Code/Calibration	Received command to take arm bp
048 Right Common Optimal	B 12:33.50 BBA13053400130533093082132068
080 Right Bulb Optimal	
112 Right Internal	Ready to take blood pressure
084 Right Bulb Far	
092 Right Bulb Near	

The 486 computer is now ready for the standard procedure for a B-mode ultrasound scan of the right side. Instructions for scanning the right side are discussed in Section 8.2.

After the right scan, which may or may not include QCs, has been completed, the computer monitors will read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	Ready to take blood pressure
Press B on the IBM keyboard.	Received command to take arm bp
To CONTINUE	B 12:33.50 BBA13053400130533093082132068
press Y and ENTER on DELL/CSA keyboard	Ready to take blood pressure

Press B on the IBM keyboard.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	Received command to take arm bp
Press B on the IBM keyboard.	B 12:33.50 BBA13053400130533093082132068
To CONTINUE	Ready to take blood pressure
press Y and ENTER on DELL/CSA keyboard	Received command to take arm bp

After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	B 12:33.50 BBA13053400130533093082132068
Press B on the IBM keyboard.	Ready to take blood pressure
To CONTINUE	Received command to take arm bp
press Y and ENTER on DELL/CSA keyboard	B 12:33.50 BBA13053400130533093082132068

After the arm blood pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	B 12:33.50 BBA13053400130533093082132068
Press B on the IBM keyboard.	Ready to take blood pressure
To CONTINUE	Received command to take arm bp
press Y and ENTER on DELL/CSA keyboard	B 12:33.50 BBA13053400130533093082132068
	Ready to take blood pressure

Press Y and ENTER on the 486 computer keyboard. The **left side menu screen** will appear on the 486 monitor and will look like this:

486 Computer Monitor	IBM Computer Monitor
032 Left Common Optimal	B 12:33.50 BBA13053400130533093082132068
064 Left Bulb Optimal	Ready to take blood pressure
096 Left Internal	Received command to take arm bp
068 Left Bulb Far	B 12:33.50 BBA13053400130533093082132068
076 Left Bulb Near	Ready to take blood pressure

After the scan of the left side has been completed. The messages on the computer screens will read as follows:

486 Computer Monitor	IBM Computer Monitor
SITTING pressure	B 12:33.50 BBA13053400130533093082132068
Press S on the IBM keyboard.	Ready to take blood pressure
	Received command to take arm bp
When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	B 12:33.50 BBA13053400130533093082132068
	Ready to take blood pressure

The sonographer explains to the participant that sitting and standing blood pressures will now be taken. The sonographer should instruct the participant to rest quietly during these blood pressures and assist the participant to these positions with as little movement as possible. Following these guidelines, the sonographer then asks the participant to sit.

Press S on the IBM keyboard. The IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
SITTING pressure Press S on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	Ready to take blood pressure Received command to take arm bp B 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure Received command to take sitting bp after 30 sec.

The IBM computer will automatically wait the 30 seconds required before taking seated blood pressure, as required in the protocol. After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
SITTING pressure Press S on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	Ready to take blood pressure Received command to take sitting bp after 30 sec. S 12:33.50 BBA13053400130533093082132068

After the seated blood pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
SITTING pressure Press S on the IBM keyboard. When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	Ready to take blood pressure Received command to take sitting bp after 30 sec. S 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure

Press Y and ENTER on the 486 computer keyboard. The 486 screen will now read:

486 Computer Monitor	IBM Computer Monitor
First STANDING pressure **Press T on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on Dell/CSA keyboard**	Ready to take blood pressure Received command to take sitting bp after 30 sec. S 12:33.50 BBA13053400130533093082132068 **Ready to take blood pressure**

The sonographer asks the participant to stand. Press T on the IBM keyboard. The screen on the IBM will now read:

486 Computer Monitor	IBM Computer Monitor
First STANDING pressure **Press T on the IBM keyboard.** **When yellow cuff light stays off,** **press Y and ENTER on Dell/CSA keyboard**	Received command to take sitting bp after 30 sec. S 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure **Received command to take first standing bp after 30 sec.**

The IBM computer will automatically wait the 30 seconds required before taking the first standing blood pressure,a s required in the protocol. After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
First STANDING pressure	S 12:33.50 BBA13053400130533093082132068
Press T on the IBM keyboard.	Ready to take blood pressure
When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	Received command to take first standing bp after 30 sec.
	T 12:33.50 BBA13053400130533093082132068 A second standing bp will taken in twenty seconds

After the first standing pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
First STANDING pressure	Received command to take first standing bp after 30 sec.
Press T on the IBM keyboard.	
When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard	T 12:33.50 BBA13053400130533093082132068 A second standing bp will taken in twenty seconds
	Ready to take blood pressure

Press Y and ENTER on the 486 computer keyboard. The 486 screen will now read:

486 Computer Monitor	IBM Computer Monitor
A SECOND STANDING pressure will be taken after 20 seconds **When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard**	Ready to take blood pressure Received command to take first standing bp after 30 sec. T 12:33.50 BBA13053400130533093082132068 A second standing bp will taken in twenty seconds **Ready to take blood pressure**

The second standing blood pressure will be taken automatically at the time interval dictated by the protocol. The IBM will read:

486 Computer Monitor	IBM Computer Monitor
A SECOND STANDING pressure will be taken after 20 seconds **When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard**	Received command to take first standing bp after 30 sec. T 12:33.50 BBA13053400130533093082132068 A second standing bp will taken in twenty seconds Ready to take blood pressure **Received command to take second standing bp**

After the data has been collected, a copy of the data sent to the IBM will be copied on the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
A SECOND STANDING pressure will be taken after 20 seconds **When yellow cuff light stays off, press Y and ENTER on Dell/CSA keyboard**	A second standing bp will taken in twenty seconds Ready to take blood pressure Received command to take second standing bp **R 12.33:50 BBA13053400130533093082132068** **Press 'E' to exit the bp program**

Left Leg

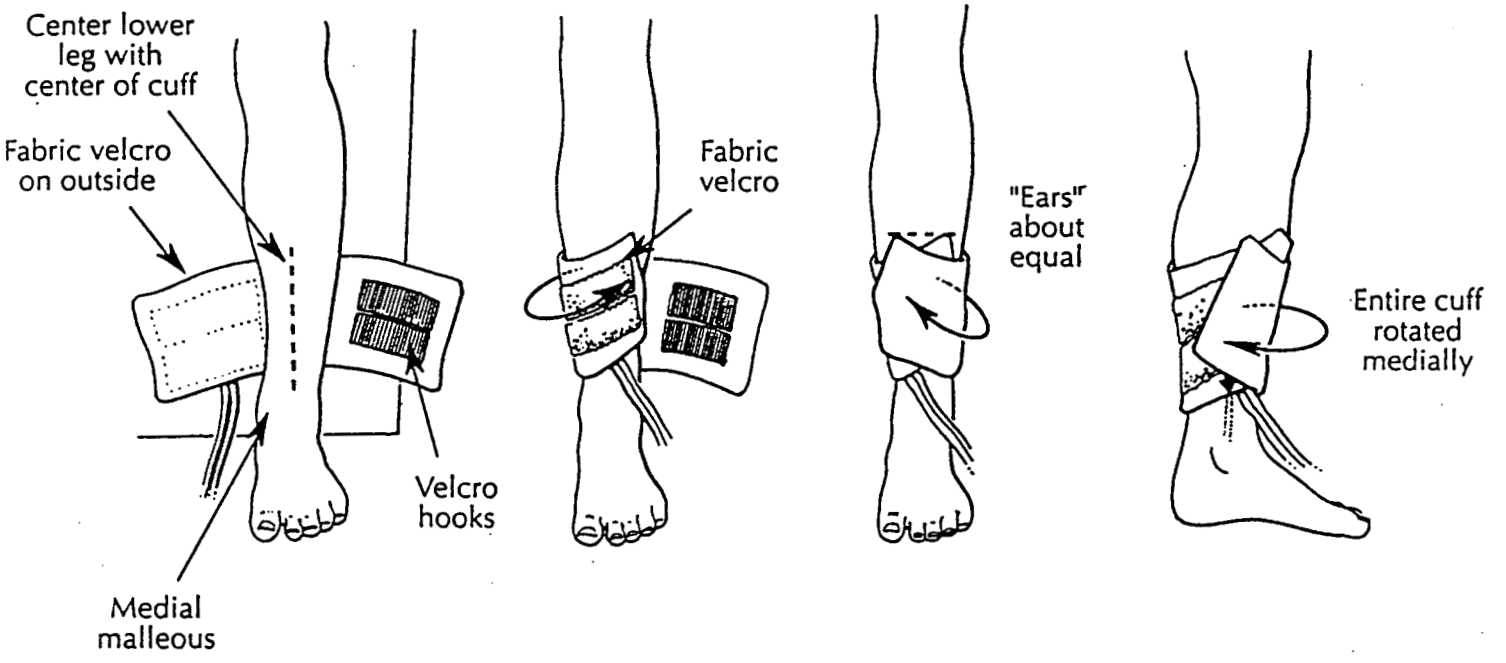


Figure 20. Blood Pressure Cuff Placement - Left Ankle

Right Leg

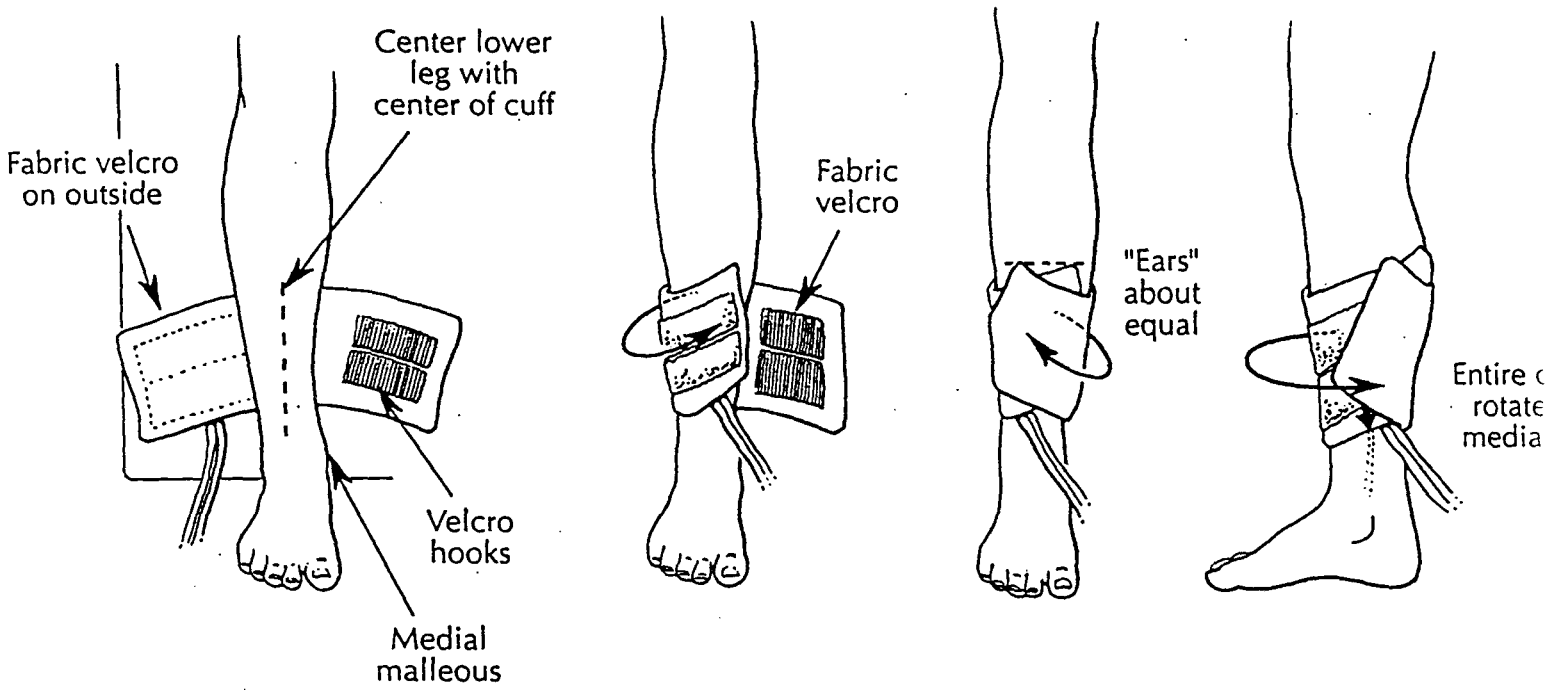


Figure 21. Blood Pressure Cuff Placement - Right Ankle

8. CAROTID SCANS

Orientation of the participant's head as follows. The participant is asked to look straight up at the ceiling. A triangular shaped, firm foam rubber wedge shaped in a 45-45-90 degree form is used to position the head in a standard way. The wedge is placed on the examination table, with largest surface of the wedge facing down. It is placed on the examination table next to the side of the neck to be evaluated in such a way that the 90# angle is furthest from the midline of the face. This positions the 45# angle closest to midline. The wedge is then gently pushed toward the midline of the head until the 45# angle edge touches the scalp. The participant is then asked to rotate his head toward the foam rubber wedge until the side of the head just above the ear rests against it. The chin may be raised slightly and the shoulder adjusted slightly for better visualization. The ultrasound equipment is positioned so that the sonographer has access to the participant's neck, all instrument controls and foot pedals.

8.1 Calibration

A calibration is done before each scan. The following settings must be followed in order to standardize the calibration procedure.

The Phase 2 settings should be as follows:

- the gain is set at 50%,
- the TGC is in a stair step alignment
- the focus is in the mid focus setting (2cm)

The transducer motor is on and there should <u>not</u> be any gel on the transducer.

The monitor displays will read as follows:

486 Computer Monitor	IBM Computer Monitor
*** PRESS RECORD TO START ***	Ready to take blood pressure
012 Start Code/Calibration	Received command to take arm bp
048 Right Common Optimal	B 12:33.50 BBA13053400130533093082132068
080 Right Bulb Optimal	
112 Right Internal	Ready to take blood pressure
084 Right Bulb Far	
092 Right Bulb Near	

Verify that 012 Start Code/Calibration is highlighted in yellow. To mark this and each following site, choose SELECT by using the SELECT footswitch. The SELECT message will appear on the flow screen for approximately 10 seconds. After pressing SELECT footswitch, wait for 7 seconds, then press NEXT SITE footswitch to move to the next site to be scanned. The yellow highlight moves to the next code, and the previous code is highlighted in green. "Do Preliminary Scan Now - Press Next Site Footswitch when finished" appears on screen of the CSA/Dell.

8.2 Right Carotid Scan

The head and neck are positioned for the exam of the right carotid. The foam rubber wedge is placed on participant's left side, and the head is rotated toward the foam rubber as outlined in the introduction to this section.

8.2.1 Preliminary

A transverse scan of the common carotid artery is performed with the patient head position and transducer interrogation angle as shown in Figure 26. The purpose of this portion of the scan is to learn the arterial geometry and orientation of the participant. Using fine transducer angulations to clearly display the blood-intima boundaries within the vessel, the transducer is slowly moved toward the mandible until the widening of the carotid bulb, and finally the internal and external carotid arteries, are visualized. Using the knowledge of the relative orientation of the internal and external carotids from this scan, the optimal angle which should best display the tip of the flow divider may be determined using the diagrams in Figures 22-25. The entire length of each carotid system is now scanned longitudinally at this optimal interrogation angle to provide an overall qualitative impression of the extent and severity of disease and the quality of the image at this interrogation angle. Unusual anatomic features or possible lesions are observed. Oral comments are recorded during the exploratory scan to assist the reader during the reading process.

8.2.4 The cursor is placed in the "Doppler" mode on the Biosound instrument panel. The sonographer determines which artery is the internal carotid artery. The cursor is first moved into one branch and then the other. The Doppler key is depressed in order to view the Doppler spectra on the Biosound screen. The Doppler key is pressed again to stop the doppler mode until the sonographer is ready to view the Doppler spectra again. This is repeated in each branch. The internal carotid artery is identified, based on the criteria outlined in Section 6.2.5. Press the **DOP CUR** key to remove the Doppler cursor from screen. The preliminary scan is complete.

8.2.5 To put the crosshair cursor on the tape for landmark identification, do the following:

a. Press the third menu key to display the Calculate menu.
b. Press the first menu key to display Distance menu.
c. Press the first menu key again for "Distance plus". The cursor will appear in the upper portion of the screen. Place cross-hair in position.
d. Adjust video gain to usual range (30-50%), and adjust TGC settings for optimal imaging. TGC - minimum on right (top), maximum on left (bottom) (stairstep configuration).

8.2.6 The sonographer verifies that the computer monitor indicates the RIGHT COMMON OPTIMAL is to be scanned.

8.2.7 The ultrasound transducer is moved proximally (toward origin - heart) to view the distal centimeter of the right common carotid artery.

The cursor is placed in the lumen as described in Section 6.3.2. The best possible image of the right common carotid artery in the optimal angle is obtained as outlined in Section 6.1 and 6.2.3.

8.2.8 The sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.2.9 When the sonographer is ready to image the next site he/she presses the NEXT SITE footswitch or presses the NEXT SITE switch on the sonographer box to advance the program to the next site. Confirm advancement of the program by verifyuing that the next site to be scanned in highlighted in yellow.

8.2.10 The transducer is moved distally to the bifurcation area. The cursor is placed at the tip of the flow divider (Section 6.3.3). The arterial interfaces are optimized at this site and angle.

8.2.11 The computer monitor indicates RIGHT BIFURCATION. The sonographer optimizes the arterial interfaces at this site, and when the best possible image is obtained as outlined in Sections 6.1 and 6.2.4, presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.2.12 When the sonographer is ready to image the RIGHT INTERNAL CAROTID, he/she presses the NEXT SITE footswitch or presses the NEXT SITE switch on the sonographer box to advance the program to the next site.

8.2.13 The transducer is moved distally to the proximal centimeter of the internal carotid artery.

8.2.14 The computer monitor indicates RIGHT INTERNAL CAROTID. The cursor is placed into the correct position at the tip of the flow divider as discussed in Section 6.3.4. The sonographer optimizes the far wall arterial interfaces. When the best possible image, as outlined in Sections 6.2.2 and 6.2.5, are obtained, the sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.2.15 When the sonographer is ready to image the RIGHT BIFURCATION FAR WALL, he/she presses the NEXT SITE footswitch or presses the NEXT SITE switch on the sonographer box to advance the program to the next site.

8.2.16 The computer monitor indicates RIGHT BIFURCATION FAR WALL, OPTIMAL ANGLE. The transducer is moved back to the bifurcation area to obtain an image of the bifurcation at the optimal angle. The cursor is placed at the tip of the flow divider (Section 6.3.3). The transducer is slowly tilted along the arterial axis so that the far wall of the bifurcation becomes vertical in the center of the display screen. The sonographer optimizes the intima-media interfaces on the far wall. During this maneuver, the near wall echoes will deteriorate. When the far wall interface echoes are optimized, as outlined in Section 6.2.6.1, the sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.2.17 When the sonographer is ready to image the RIGHT BIFURCATION NEAR WALL, he/she presses the NEXT SITE footswitch or presses the NEXT SITE switch on the sonographer box to advance the program to the next site.

8.2.18 The computer monitor should indicate the RIGHT BIFURCATION NEAR WALL, OPTIMAL ANGLE. The transducer is slowly tilted along the arterial axis back towards the optimal angle and then beyond so that the near wall of the bifurcation becomes vertical in the center of the display screen. The cursor is placed at the tip of the flow divider (Section 6.3.3). The sonographer optimizes the media-intima interfaces on the near wall. During this maneuver, the far wall echoes will deteriorate. When the near wall interface echoes are optimized, as outlined in Section 6.2.6.2, the sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape. The sonographer removes the transducer from the neck and presses the NEXT SITE footswitch.

8.2.19 The sonographer looks at the computer monitor to see if a site will be repeated on the right side for quality assurance purposes (QC site). If no QC site scan is required on the right side, the sonographer presses the NEXT SITE footswitch again.

8.2.20 If a QC site scan is required, the monitor displays, in red, the QC site and the flow screen highlights the code. The sonographer obtains an image of the QC site and angle; moves the cursor to the appropriate landmark and optimizes the arterial interfaces. When the best possible image has been obtained, he/she presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.2.21 The sonographer presses NEXT SITE switches on the sonographer box or on the NEXT SITE footswitch.

8.2.22 The gel is wiped from the participant's neck, and the head and neck are repositioned for the left side scan.

8.2.23 The arm blood pressure screen will appear. The sonographer should follow directions on the screen to complete blood pressure measurement.

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	B 12:33.50 BBA13053400130533093082132068
Press B on the IBM keyboard.	Ready to take blood pressure
To CONTINUE	Received command to take arm bp
Press Y and ENTER on DELL/CSA computer.	B 12:33.50 BBA13053400130533093082132068 **Ready to take blood pressure**

Press B on the IBM computer keyboard. The screens will now read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	Ready to take blood pressure
Press B on the IBM keyboard.	Received command to take arm bp
To CONTINUE	B 12:33.50 BBA13053400130533093082132068
Press Y and ENTER on DELL/CSA computer.	Ready to take blood pressure
	Received command to take arm bp

After the data has been collected, a copy of the data sent to the IBM will be copied onto the IBM monitor. The data displayed will look something like this:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	Received command to take arm bp
Press B on the IBM keyboard.	B 12:33.50 BBA13053400130533093082132068
To CONTINUE	Ready to take blood pressure
Press Y and ENTER on DELL/CSA computer.	Received command to take arm bp
	B 12:33.50 BBA13053400130533093082132068

After the arm blood pressure is taken and the cuff is fully deflated, the IBM screen will read:

486 Computer Monitor	IBM Computer Monitor
COMPUTER ARM	B 12:33.50 BBA13053400130533093082132068
Press B on the IBM keyboard.	Ready to take blood pressure
To CONTINUE	Received command to take arm bp
Press Y and ENTER on DELL/CSA computer.	B 12:33.50 BBA13053400130533093082132068
	Ready to take blood pressure

Press Y and ENTER on the 486 computer keyboard. The 486 screen will now read:

486 Computer Monitor	IBM Computer Monitor
*DO PRELIMINARY SCAN NOW * PRESS NEXT SITE WHEN DONE	B 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure Received command to take arm bp B 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure

8.2.24 The sonographer now enters comments on log sheet for reference later when computer comments will be required. Please note that the VCR will continue in RECORD mode.

8.3 Left Carotid Scan

8.3.1 The head and neck are positioned for the exam of the left carotid. The foam rubber wedge is placed on the participant's right side and the head is rotated toward the foam rubber pillow as outlined in the introduction of this section.

8.3.2 "Do Preliminary Scan now, press next site when done" message appears on monitor.

8.3.3 A transverse scan of the common carotid artery is first performed with the patient head position and transducer interrogation angle as shown in Figures 26-29. Using fine transducer angulations to clearly display the blood-intima boundaries within the vessel, the transducer is slowly moved toward the mandible until the widening of the carotid bulb, and finally the internal and external carotid arteries, are visualized. Using the knowledge of the relative orientation of the internal and external carotids from this scan, the optimal angle which should best display the tip of the flow divider may be determined using the diagrams in Figures 26-29. The entire length of each carotid system is now scanned longitudinally at this optimal interrogation angle to provide an overall qualitative impression of the extent and severity of disease and the quality of the image at this interrogation angle. Unusual anatomic features or possible lesions are observed. Oral comments are recorded during the exploratory scan to assist the reader during the reading process.

8.3.4 The cursor is placed in the "Doppler" mode on the Biosound instrument panel. The sonographer determines which artery is the internal carotid artery. The cursor is first moved into one branch and then the other. The Doppler key is depressed in order to view the Doppler spectra on the Biosound screen. The key is depressed again to stop the Doppler. This is repeated in each branch. The internal carotid artery is identified, based on the criteria outlined in Section 6.2.5.

8.3.5 The sonographer verifies that the computer monitor indicates the LEFT COMMON OPTIMAL is to be scanned.

8.3.6 The ultrasound transducer is moved proximally to view the distal centimeter of the common carotid artery. The cursor is placed in the lumen (Section 6.3.2). The best possible image of the left common carotid artery in the optimal angle is obtained, as outlined in Sections 6.1 and 6.2.3 and shown in Figure 19.

8.3.7 The sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.3.8 When the sonographer is ready to image the LEFT BIFURCATION, he/she presses NEXT SITE footswitch, or, NEXT SITE on the sonographer box to advance the program to the next site.

8.3.9 The transducer is moved distally to the bifurcation area. The cursor is placed at the tip of the flow divider (Section 6.3.3). The sonographer optimizes the arterial interfaces at this site and angle.

8.3.10 The computer monitor indicates LEFT BIFURCATION. The sonographer optimizes the arterial interfaces at this site, and when the best possible image is obtained, as outlined in Sections 6.1 and 6.2.4, presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.3.11 When the sonographer is ready to image the LEFT INTERNAL CAROTID, he/she presses NEXT SITE footswitch, or, NEXT SITE on the sonographer box to advance the program to the next site.

8.3.12 The sonographer moves the transducer distally to the proximal centimeter of the internal carotid artery.

8.3.13 The computer monitor indicates LEFT INTERNAL CAROTID. The cursor is placed into the correct position to indicate the tip of the flow divider as discussed in Section 6.3.4. The sonographer optimizes the far wall arterial interfaces, and when the best possible image is obtained, as outlined in Sections 6.2.2 and 6.2.5, presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.3.14 When the sonographer is ready to image the LEFT BIFURCATION FAR WALL, he/she presses NEXT SITE footswitch, or, NEXT SITE on the sonographer box to advance the program to the next site.

8.3.15 The computer monitor indicates the LEFT BIFURCATION FAR WALL, OPTIMAL ANGLE. The transducer is moved back to the bifurcation area to obtain an image of the bifurcation at the optimal angle. The cursor is placed at the tip of the flow divider (Section 6.3.3). The transducer is slowly tilted along the arterial axis so that the far wall of the bifurcation becomes vertical in the center of the display screen. The sonographer optimizes the intima-media interfaces on the far wall. During this maneuver, the near wall echoes will deteriorate. When the far wall interface echoes are optimized, as outlined in Section 6.2.6.1,

the sonographer presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.3.16 When the sonographer is ready to image the LEFT BIFURCATION, NEAR WALL, he/she presses NEXT SITE footswitch, or, NEXT SITE on the sonographer box to advance the program to the next site.

8.3.17 The computer monitor indicates the LEFT BIFURCATION NEAR WALL, OPTIMAL ANGLE. The transducer is slowly tilted along the arterial axis back toward the optimal angle and then beyond, so that the near wall of the bifurcation becomes vertical in the center of the display screen. The cursor is placed at the tip of the flow divider (Section 6.3.3). The sonographer optimizes the media-intima interfaces on the near wall as outlined in Section 6.2.6.2. During this maneuver, the far wall echoes will deteriorate. When the near wall interface echoes are optimized, the SELECT footswitch is pressed and the image is held in view for at least five consecutive cardiac cycles, marking the site on video tape. The sonographer removes the transducer from the neck.

8.3.18 The sonographer looks at the PC to see if a site will be repeated on the left side for quality assurance purposes (QC site). If no QC site scan is required on the left side, the sonographer presses the NEXT SITE footswitch.

8.3.19 If a QC site scan is required, the monitor displays, in red, the QC site and the flow screen highlights the code. The sonographer obtains an image of the QC site and angle; moves the cursor to the appropriate landmark and optimizes the arterial interfaces. When the best possible image has been obtained, he/she presses the SELECT footswitch and holds the image for at least five cardiac cycles, marking the site on video tape.

8.3.20 The NEXT SITE footswitch is pressed twice to advance the program to the option screen for distensibility, which will appear as follows:

486 Computer Monitor	IBM Computer Monitor
DISTENSIBILITY TRACKING **TRACK LEFT SIDE** **EXIT OR SKIP DISTENSIBILITY**	B 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure Received command to take arm bp B 12:33.50 BBA13053400130533093082132068 Ready to take blood pressure

Use the arrow key to highlight **EXIT OR SKIP** in yellow, and press **ENTER** to advance the program and wipe gel from the participant's neck.

The messages on the computer screen will prompt the sonographer to execute sitting and standing blood pressures, as described in Section 7.5.

8.3.21 Once the automatic blood pressure is finished, the participant is thanked for their cooperation and escorted from the room.

8.3.22 The sonographer presses Y and ENTER on the 486 keyboard. The 486 screen will now read:

486 Computer Monitor	IBM Computer Monitor
Press E to Exit on IBM	A second standing bp will taken in twenty seconds
When you see the C:\ on the IBM	Ready to take blood pressure
Press Y and ENTER on the DELL/CSA	Received command to take second standing bp
	R 12.33:50 BBA13053400130533093082132068 Press 'E' to exit the bp program

Press E on the IBM keyboard. The IBM blood pressure program is automatically exited. The program creates a file containing the recorded blood pressures, which is placed in the study's directory. The file is named with the participant ID as the file name and bp as its extension, i.e., X******.bp, where X represents the field center code, and the asterisks represent the participant ID number.

8.3.23 When the "Comments" screen appears, the sonographer types his/her comments for the left side images, and presses ENTER to advance the program.

8.4 Question Screens

Following "comments" is a series of question screens. The sonographer uses the ARROW key to select the appropriate answer, and presses ENTER to advance to the next screen.

8.5 Ultrasound Conclusion

Upon completion of the final question screen, the program automatically copies all the participant files from the hard drive to the diskette. The sonographer applies labels appropriately and fills out the log sheet (See Section 11).

Copy the blood pressure files onto a 5 1/4" floppy diskette. This 5 1/4" floppy and the 3 1/2" floppy containing the participant files, should be sent along with the videotape to the Ultrasound Reading Center.

In addition, a 5 1/4" floppy containing a backup copy of the blood pressure files should be stored at the field center.

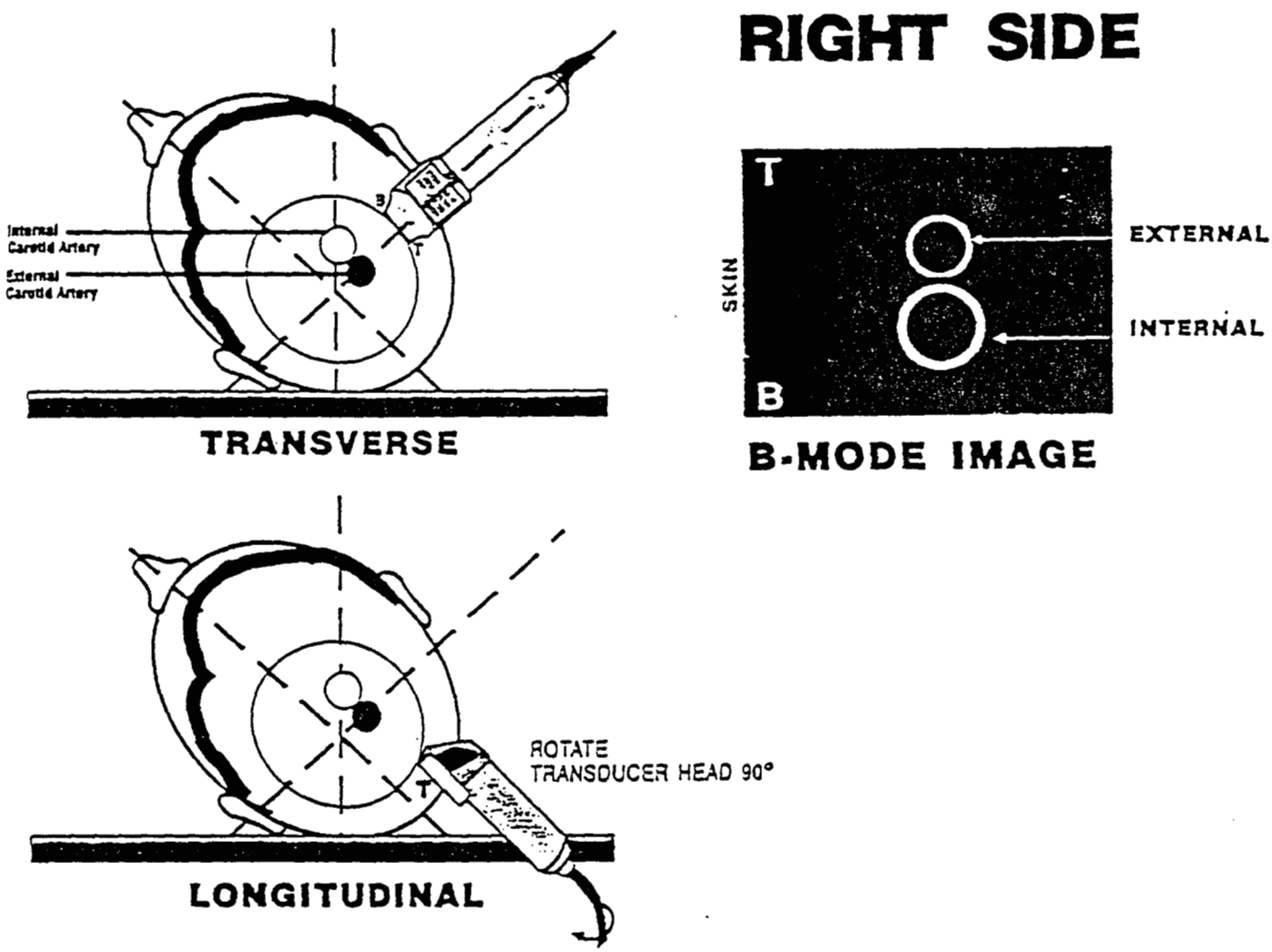


Figure 22. Right Carotid Artery - Transverse Scan Investigation Procedure

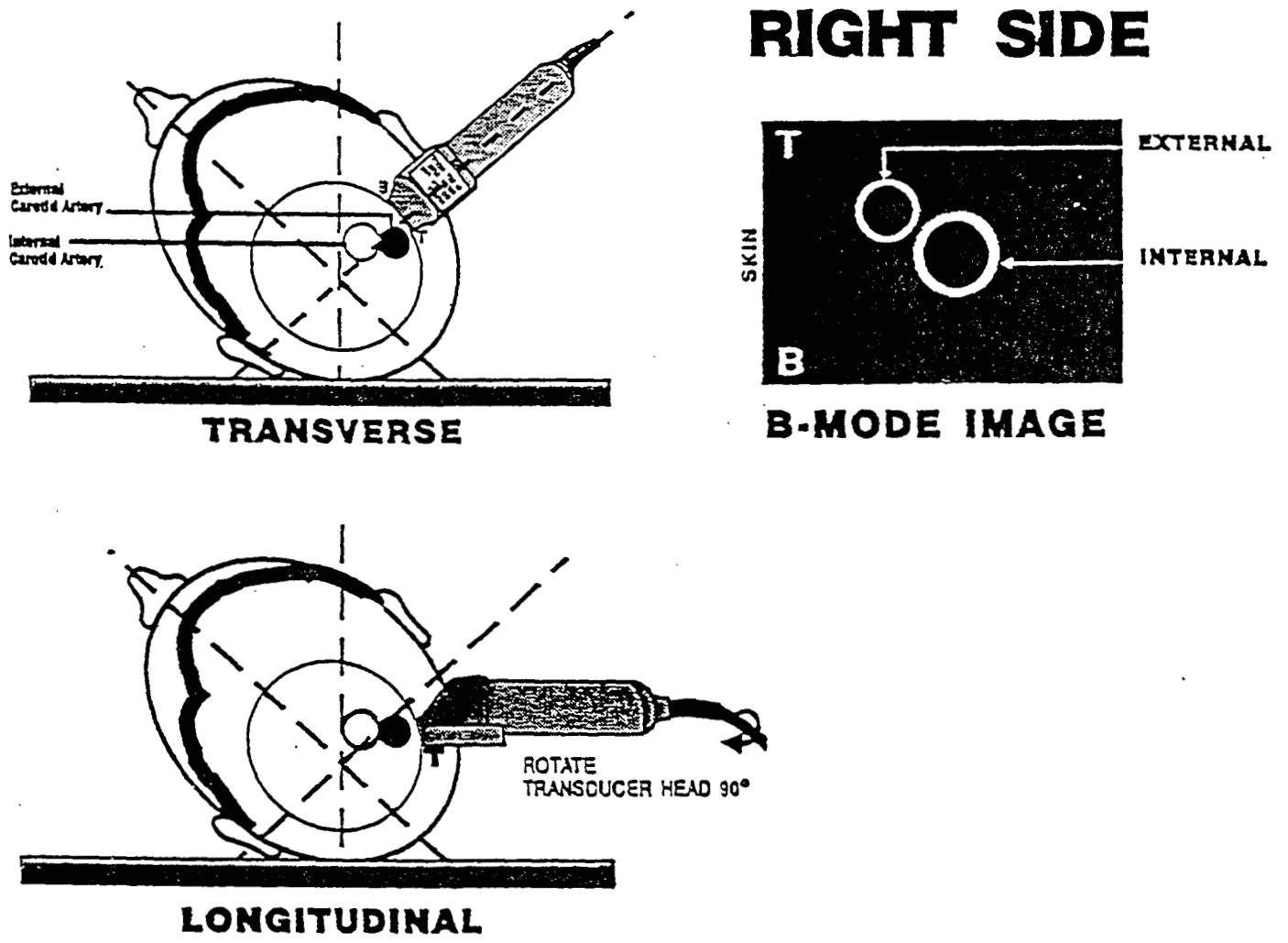


Figure 23. Right Carotid Artery - Transverse Scan Investigation Procedure

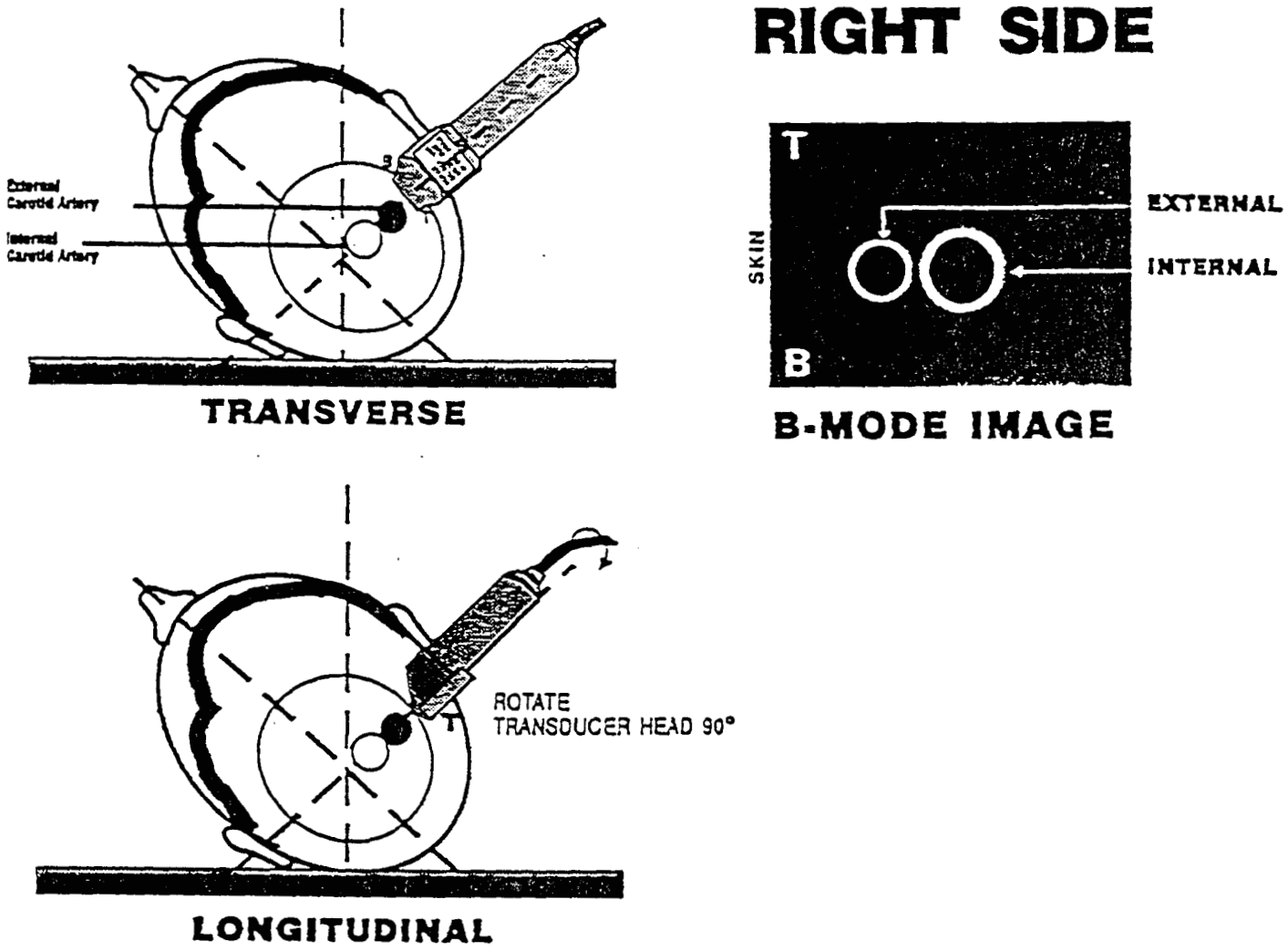


Figure 24. Right Carotid Artery - Transverse Scan Investigation Procedure

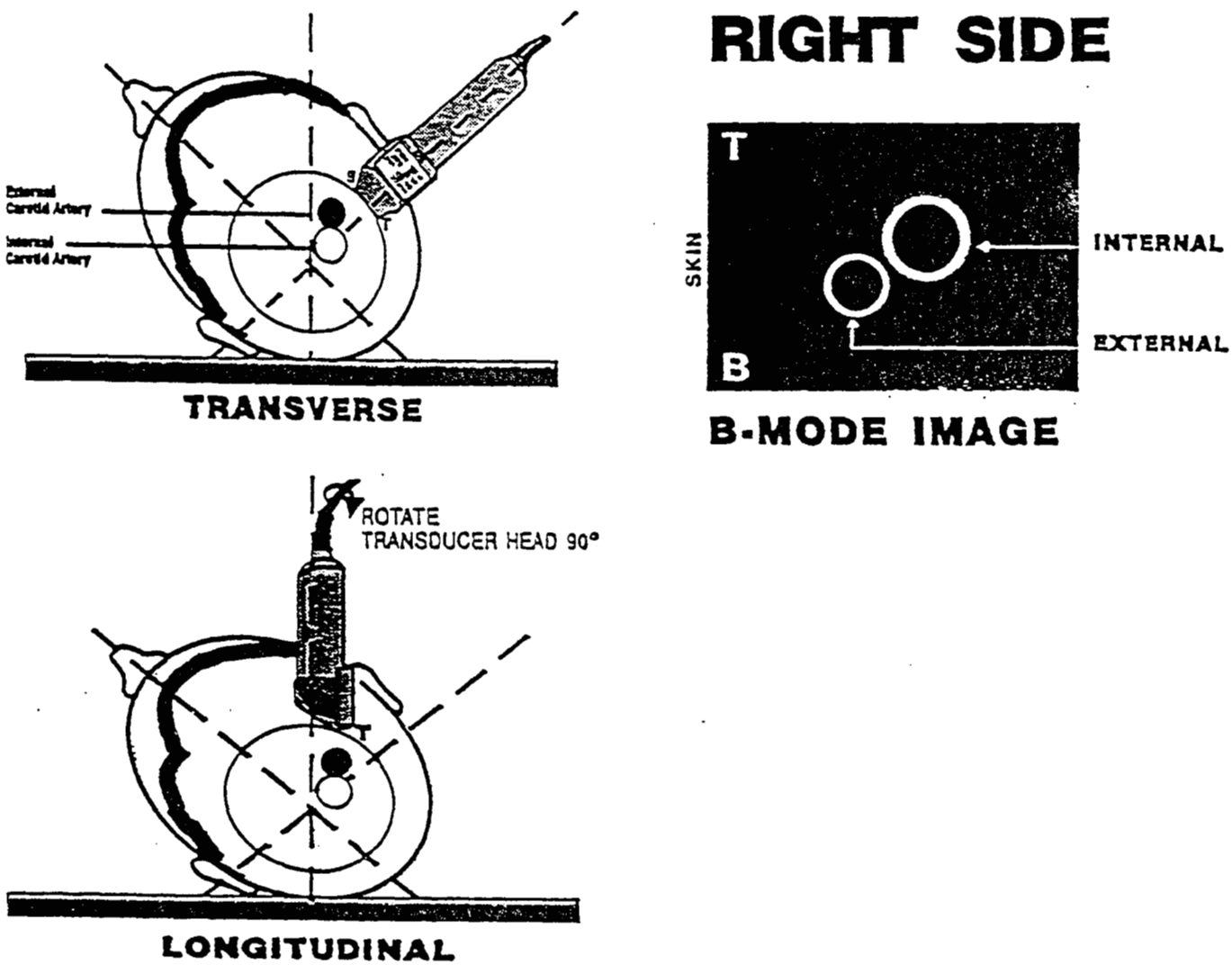


Figure 25. Right Carotid Artery - Transverse Scan Investigation Procedure

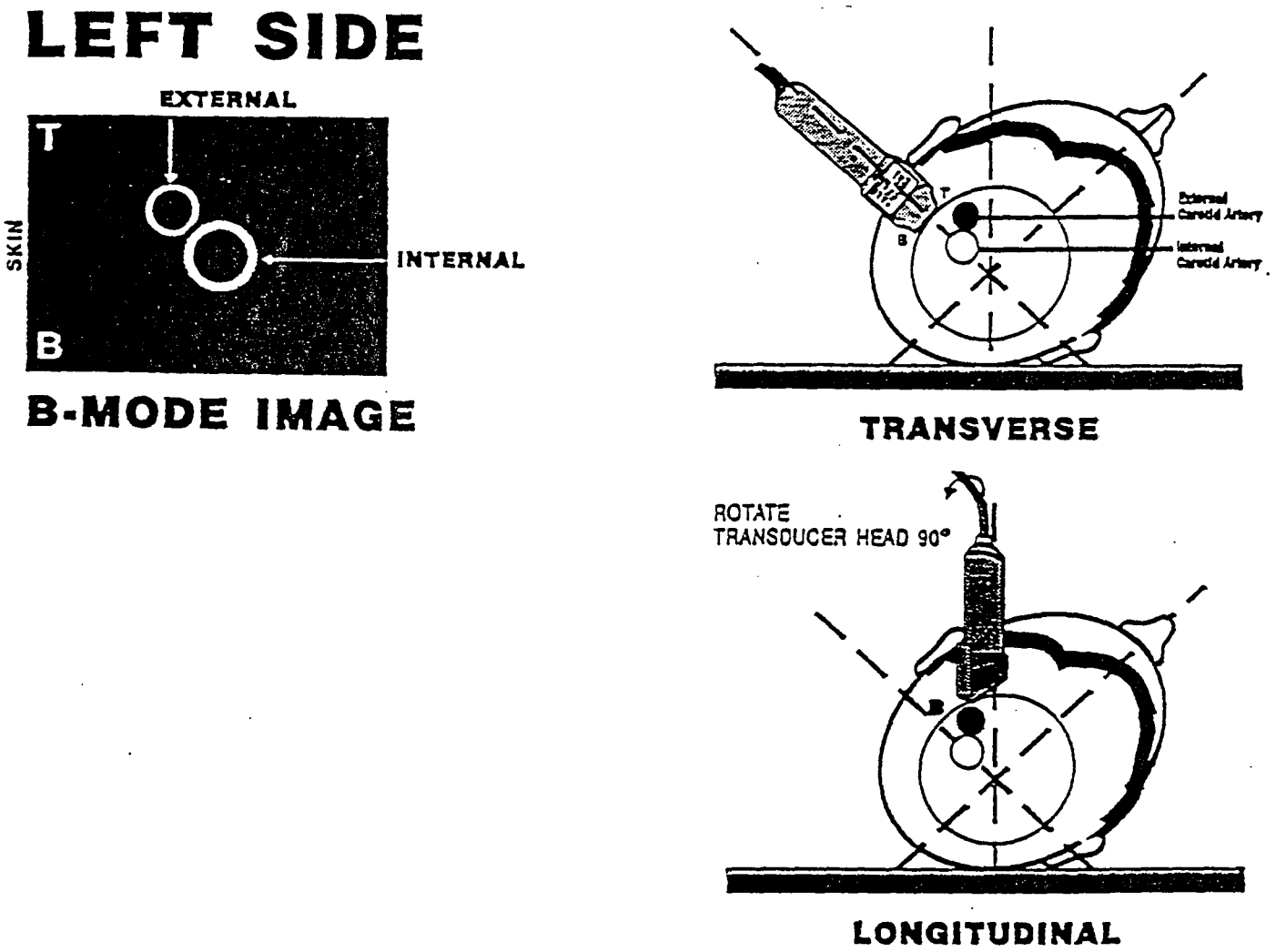


Figure 26. Left Carotid Artery - Transverse Scan Investigation Procedure

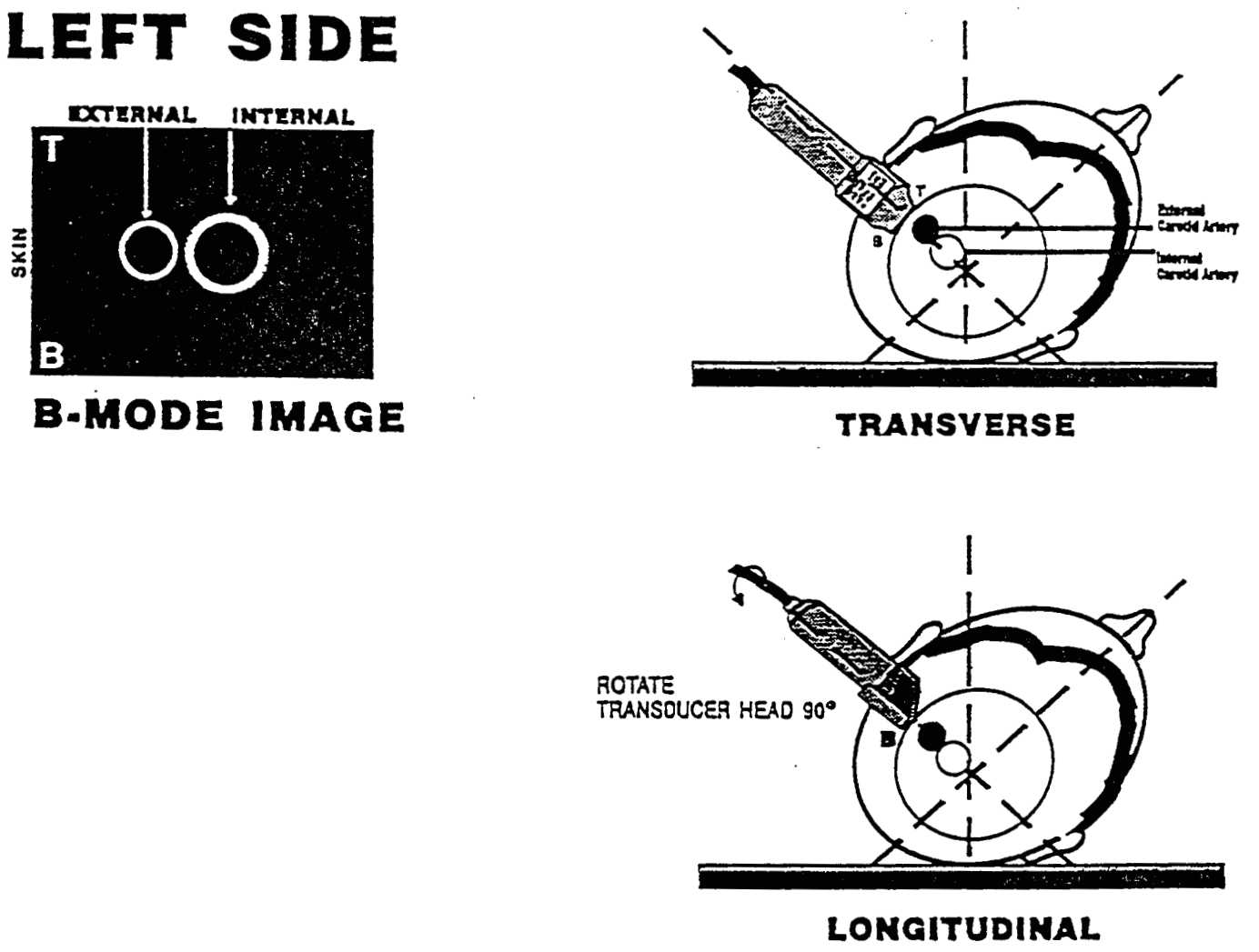
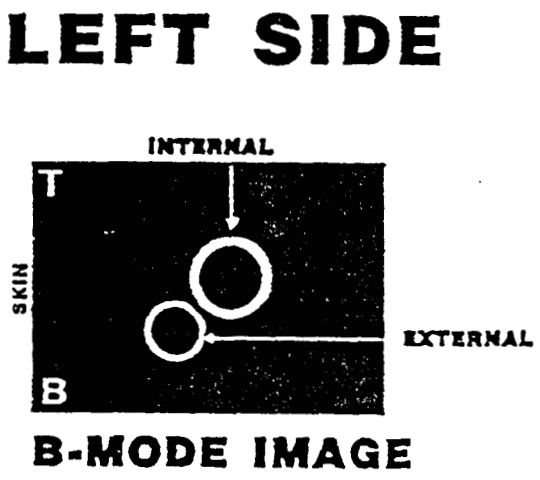
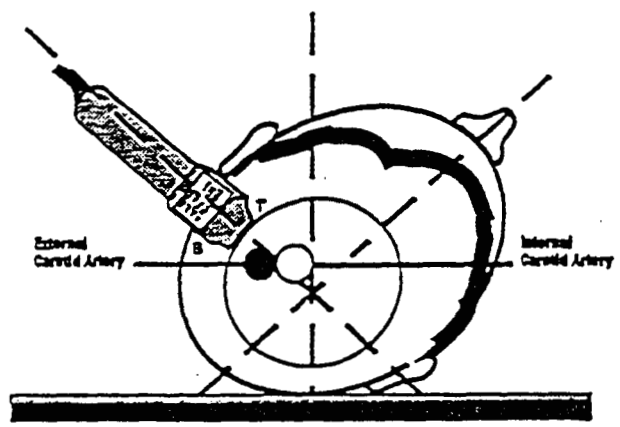


Figure 27. Left Carotid Artery - Transverse Scan Investigation Procedure





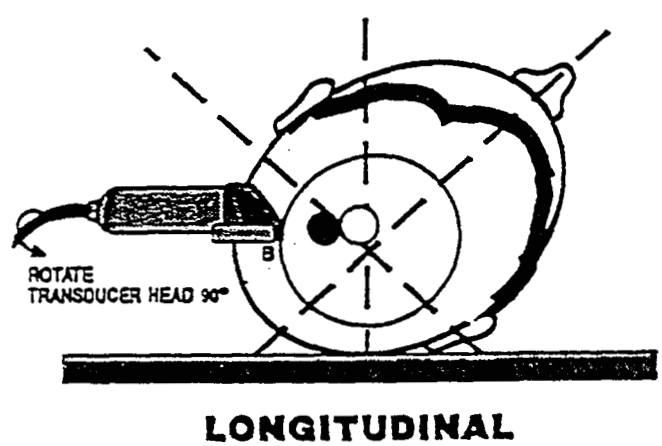


Figure 28. Left Carotid Artery - Transverse Scan Investigation Procedure

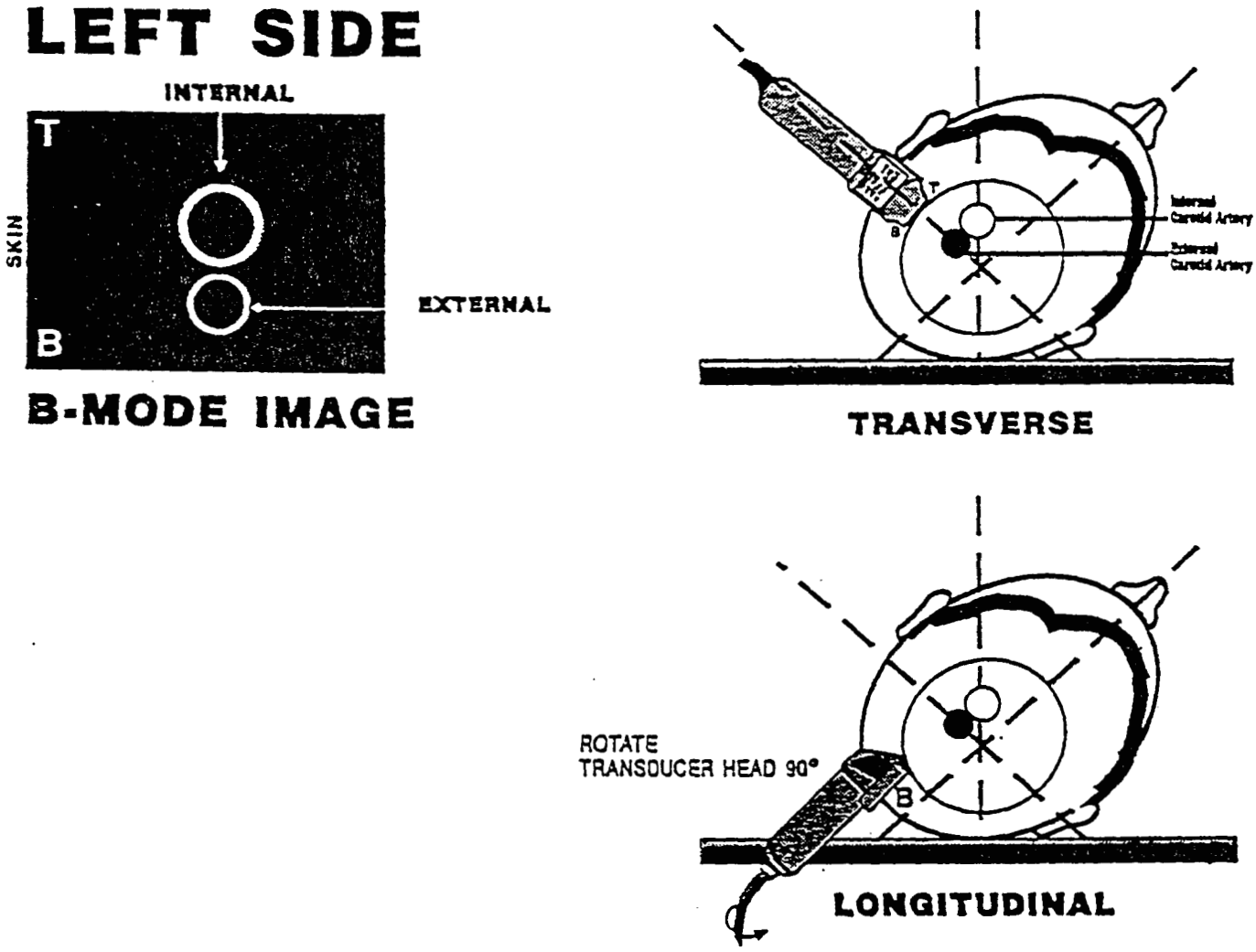


Figure 29. Left Carotid Artery - Transverse Scan Investigation Procedure

9. SONOGRAPHER TRAINING, CERTIFICATION AND MONITORING

9.1 Training

The sonographer training program includes training sessions held at the respective field centers and the Ultrasound Reading Center, followed by practice scans at the respective field centers and certification steps at the field centers.

9.1.1 Stage 1

During the initial weeks, a new sonographer works with the certified sonographers at the field center to observe the ultrasound area activities, become familiar with the equipment, read the introductory material supplied by the URC, and become familiar with this scanning protocol.

9.1.2 Stage 2

The second phase (approximately 80 hours) at the Ultrasound Reading Center consists of lectures, demonstrations, and practical laboratory experience on the following topics:

a. Overview of the Study.
b. Role of the Ultrasound Reading Center.
c. Ultrasonic Physics I, including basic physics concepts, units of measurement, and mathematics arising in the medical applications of ultrasound.
d. Overview of atherosclerosis and a detailed discussion of the normal artery wall.
e. Ultrasonic Physics 2, including a discussion of the properties of ultrasonic waves, reflection at boundaries and scattering from small objects.
f. Ultrasonic Physics III, including the Doppler effect, ultrasound transducers and sound beams.
g. Pathology of Atherosclerosis.
h. Principles of Ultrasonic Instrumentation, including pulse-echo imaging systems, pulsed Doppler systems, and spectral analysis.
i. Basic operation of the Biosound Phase 2.
j. Instrument Performance Monitoring.
k. Basic Operation of the Custom Study Equipment
l. Principles of Ultrasound Arterial Scanning.

The remaining training time (at least 15 hours) at the field center will be spent practicing scanning technique on volunteers with the protocol, including the use of the study flow program and personal computer. The field center coordinator and the chief sonographer need to help the novice sonographers in their recruitment and provide scheduled time for at least one volunteer practice scan per day. The chief sonographer determines when the new sonographer has attained sufficient skills to produce a scan according to this protocol. This portion of training is done under the direct supervision of the chief sonographer who guides, evaluates, offers suggestions for improvements and answers questions as they arise.

9.1.3 Stage 3

When the chief sonographer determines the new sonographer is ready, the new sonographer scans volunteers with minimum supervision from the chief sonographer. When the chief sonographer has reviewed 5 practice scans that comply with the standards of quality of interfaces, image alignment, cursor placement, interrogation angles and overall quality of scanning, and the new sonographer has demonstrated that she can perform a scan which conforms to protocol within the time allotted by her field center for an ultrasound scan, the chief sonographer notifies the Ultrasound Reading Center that the sonographer has completed the practice phase.

9.1.4 Stage 4

After completion of the practice phase, the new sonographer performs no more than two scans per day on adult volunteers. At least ten scans are performed in this mode. All such studies are identified and sent to the URC for evaluation along with the normal weekly shipment of tapes. The scans subject to this evaluation are scans for which the ultrasound equipment is working properly and study participants have arteries and anatomy which permit the walls to be adequately visualized. These scans will be evaluated by the lead study sonographer (or his/her designee) for effective adherence to protocol. During this stage, feedback on this process will be given to the trainee. When ten scans have conformed to the study standards, the sonographer will be certified to scan participants in this study, and have the data resulting from those scans entered into the study database.

9.2 Certification

9.2.1 Certification of Experienced Sonographers

A sonographer attains certification to scan based upon her ability, while following the ARIC/FHS scanning protocol, to visualize arterial walls consistent with the process average of all sonographers certified in Visits one and two of ARIC, as indicated by paired points marked by certified readers at the Ultrasound Reading Center. The monthly review of the scan, by the lead sonographer and chief sonographer, must, on average, meet scanning standards. As long as a sonographer maintains visualization consistent with the process average of her peers, and, the average of monthly review scans meet protocol standards, she retains certification.

9.2.2 Certification of New Sonographers

When the novice sonographer has successfully met all training requirements, as outlined in Section 9.1, written notification is sent to him/her and to the chief sonographer at his/her field center, informing the new sonographer of his/her new status as a certified sonographer.

9.2.3 Guest Sonographers

During the course of this Study it is expected that, upon occasion, a sonographer will be unavailable to scan participants without being able to give sufficient prior notice to allow for a reschedule of the participant's visit. If no provision were made for such an eventuality, participant's would be unduly inconvenienced, or may refuse to return to undergo an ultrasound evaluation. In such a case, in order to prevent a loss of valuable data, the services of a guest sonographer may be used. A guest sonographer is one who is well-versed in the applied principles of carotid ultrasound, and who is familiar with the ARIC/FHS ultrasound scanning protocol and study equipment. The names and qualifications of guest sonographers are to be registered with the Ultrasound Reading Center, where they will be assigned ID numbers.

Prior to substituting for a certified sonographer for this Study, the guest sonographer is to re-read the protocol, and review it with the chief sonographer or, in her absence, another ARIC/FHS certified sonographer. Tapes containing scans recorded by the guest sonographer are to be clearly marked to that effect. Likewise, a notation is to be made on the log sheet.

Upon receipt of these tapes at the Ultrasound Reading Center, these tapes will not be logged in with the tapes produced by certified sonographers. They will first be reviewed by a certified reader. If the scans are found to conform to protocol, they will be logged in and treated from then on in the standard fashion. If, however, the scans are found not to conform to protocol, the scans will not be logged in and will not be read. The field center coordinator, chief sonographer and guest sonographer will be informed of the areas where the scan did not conform to the protocol.

Due to the additional effort required to process these scans, no guest sonographer may scan for more than five days or fifteen scans within a two month period without first obtaining special permission from the Executive Committee of this Study. Should a field center require additional sonographer support for an extended period, guest sonographers must undergo additional training as specified by the Ultrasound Reading Center in order to become certified for this study.

9.2.4 Loss of Certification

When a sonographer's average monthly boundary visualization falls significantly below the process average for one site, by a small amount for a number of sites, if the visualization report reveals any trend toward a loss of visualization, or if the scans produced deviate from protocol, or, the average monthly scans reviewed do not meet protocol standards, she and her chief sonographer will be notified of the specific nature and extent of loss of consistency so that remedial steps can be taken to improve visualization in those sites.

9.2.5 Scanning Process Control

The methods employed by the Ultrasound Reading Center for assuring the quality of ultrasound data are based on the work of F. Edwards Demming, J.M. Juran and Ellis Ott. Tools include process capability and statistical process control charting techniques, with consistent performance and constant improvement as goals.

Timely feedback is critical to the success of this procedure. Therefore, on a routine basis, based on frequency of scanning and sonographer consistency, sonographers will be given detailed reports of their performance, and be notified of the extent to which they conform to the quality and quantity of data gathering exhibited by the Study sonographers as a group. Below are indicated the steps to be followed based on each sonographer's conformance to these standards.

9.2.6 Conforming

- The sonographer, chief sonographer and study coordinator will receive written notification of her scanning performance.
- The sonographer will continue to scan.
- The URC will continue to monitor levels of visualization.

9.2.7 Non-conforming - slight

- The sonographer, chief sonographer and study coordinator will receive written notification of her scanning performance.
- The chief sonographer will check equipment performance and preventive maintenance record.
- The sonographer will review the scanning protocol with the chief sonographer.
- The chief sonographer will observe the sonographer perform that part of the scan which was found not to conform to standards.
- The sonographer will discuss with the chief sonographer ways to improve visualization at the specific site(s).
- The sonographer will report back to the URC on the steps taken to effect the improvement.
- The sonographer will continue to scan.
- The URC will continue to monitor levels of visualization.

9.2.8 Non-conforming - moderate

- The sonographer, chief sonographer and study coordinator will receive written notification of the sonographer's scanning performance.
- The chief sonographer will check equipment performance and preventive maintenance record.
- The sonographer will review the scanning protocol with the chief sonographer.
- The sonographer will review training materials on the principles of physics and anatomy.
- The chief sonographer will observe the sonographer perform that part of the scan which was found not to conform to standards.
- The lead study sonographer will identify patterns which might reveal the reason for failing to conform to the standard, document

areas in need of improvement, and communicate her findings to the sonographer.

- The sonographer and chief sonographer will discuss ways to improve visualization at the specific sites.
- The sonographer will practice that part of the scan on volunteers.
- The sonographer will report back to URC on steps taken to effect improvement.
- The sonographer will continue to scan.
- The URC will continue to monitor levels of visualization.

9.2.9 Non-conforming - severe

- The sonographer, chief sonographer and study coordinator will receive written notification of the sonographer's scanning performance.
- The sonographer will stop scanning cohort participants immediately.
- The chief sonographer will check equipment performance and preventive maintenance record.
- The lead study sonographer will identify patterns which might reveal the reason for failing to conform to the standard, document areas in need of improvement, and communicate her findings to the sonographer.
- The sonographer will review training materials on the principles of physics and anatomy.
- The sonographer will review the scan protocol with the chief sonographer.
- The chief sonographer will observe the sonographer as he/she performs that part of the scan which was found not to conform to standards.
- The sonographer and the chief sonographer will discuss ways to improve visualization at those specific sites.
- The sonographer will produce a taped scan of a volunteer of cohort age. The sonographer will then make practice scans on volunteers. When the chief sonographer determines that sufficient improvement has been made, the sonographer will make another taped scan of the same initial volunteer. Both tapes will be sent to the UC for evaluation.
- The sonographer will report back to URC on steps she has taken to effect improvement.
- When the URC determines that improvement has been demonstrated, with visualization at or above the study average for all sites, the sonographer, chief sonographer and field center coordinator will be notified, and the sonographer may then resume scanning.
- The URC will continue to monitor levels of visualization.

9.3 Monitoring

Sonographer performance is monitored throughout the Atherosclerosis Risk in Communities Study at the respective field centers and the Ultrasound Reading Center.

9.3.1 Monitoring at Field Center

Each month the chief sonographer reviews one scan per sonographer for his/her field center. The primary purpose for review is to ensure the quality of the study data and adherence to the scanning protocol. The B-mode images are evaluated for overall image quality, the presence and clarity of the arterial wall boundaries, and the presence of anatomical landmarks and a cursor indicating the location of an anatomical landmark and the vessel lumen.

The time of the month for sonographer review for each sonographer is determined by the chief sonographer, but is not the same from month to month. All reviews are sent to the URC before and no later than the end of the third week of that month. It is recommended by the Ultrasound Reading Center that only one review per week be performed to reduce the time commitment during any one week. The chief sonographer keeps a log of the review and discusses her findings with the sonographer on a timely basis.

9.3.2 Monitoring at the Ultrasound Reading Center

Sonographer performance is monitored at the Ultrasound Reading Center using a number of quality assurance procedures. The quality assurance procedures include but are not limited to: (1) comparing results of repeat studies on a randomly selected identical site and angle of individual participants; (2) periodic reports containing statistics of boundary visualization by individual sonographer and study wide; (3) visual review of randomly selected participant scans; (4) on-site monitoring of sonographer performance by designated URC personnel. Reports are generated and distributed by the Ultrasound Reading Center.

In addition, the Ultrasound Reading Center can review the same participant studies reviewed by the chief sonographers at the field centers. The sonographer evaluation form is completed at the URC, and the results are compared to the chief sonographer's form. Any significant differences between evaluations, or any significant problems are discussed with the chief sonographers to resolve the differences. Results of these sonographer evaluations are used to help maintain high standards for participant studies and are part of an ongoing sonographer recertification process.

The Ultrasound Reading Center readers read the ultrasound images from all the data collection procedures and the quality assurance images. Image interpretation results from study images and quality assurance images from the same site and angle are compared for use in sonographer quality assurance procedures. The purpose of this evaluation procedure is to determine the consistency and reproducibility of scanning and of interpreting ultrasound images. The results of these evaluations are reported periodically to the ARIC Coordinating Center and the field centers.

9.4 The B-Mode Study Scan Evaluation Form

The current version of the B-mode study scan evaluation form is on file at the Ultrasound Reading Center in Winston-Salem, NC. This form provides a forum for a detailed accounting of the conformance to scanning protocol as described in this document.

9.5 The Lead Study Sonographer

The Ultrasound Reading Center is responsible for pre-certification, certification and re-certification of sonographers. Certifying processes involve the review and evaluation of B-mode scans, as well as statistical evaluation of sonographer performance. The lead study sonographer provides feedback to the sonographer, his/her chief sonographer and to the Ultrasound Coordinator. This feedback to the sonographer includes, but is not limited to, site visits, verbal communication over the phone or in the form of taped comments of reviewed scans, written communication, in the form of formal reviews of scans, statistical evaluations of performance and recertification reports.

10. SUMMARY OF CHIEF SONOGRAPHER DUTIES

The chief sonographers' duties are a vital part of maintaining the quality of the ultrasound data at the field centers. The estimated time-effort required, exclusive of training new sonographers, is 10 percent. A summary of duties is listed below.

a. Assists the Ultrasound Reading Center in training new sonographers as described in Section 9.1.3, Stage 3.

b. Responsible for reviewing sonographer scanning performance as described in Section 9.3.1.

c. Responsible for reviewing the quality assurance data prepared by the Ultrasound Reading Center for the field center, and for each sonographer at that field center. Current values and trends are reviewed, and if problems arise, the chief sonographer and the Ultrasound Reading Center will work together with the sonographer to implement solutions.

d. Responsible for reporting ultrasound area equipment problems to the Ultrasound Reading Center.

e. Responsible for scheduling preventive maintenance visits and other service calls as needed. Before each visit or call to Biosound, a list of problems are written and given to them, in case special test equipment or boards are required.

f. Responsible for communication with the Ultrasound Reading Center.

g. Responsible for sonographer recertification as outlined in Section 9.

11. LABELING AND MAILING TO THE ULTRASOUND READING CENTER

11.1 Labeling of Video Cassettes and Diskettes

Video cassette and diskette labels identify the field center and are numbered sequentially. The starting number for each field center is listed below:

Forsyth ARIC/FHS:	F10001X
	F20001X
Jackson ARIC:	J30001X
Minneapolis ARIC/FHS:	M50001X
Framingham FHS:	B60001X
Salt Lake City FHS:	U80001X
Hagerstown ARIC:	W70001X

The final character, shown as an "X" here, is a code check character. Each field center maintains a log that records the video cassette number and the participant identification numbers on that cassette (Log sheet reference -- Appendix 5). The information in columns 1-10 must be included and filled out by sonographers before they send it to the Ultrasound Reading Center.

11.1.1 Each video cassette is labeled with the video cassette number and no more than four participant identification numbers. Note that the video cassette number appears only once on the short edge of the video cassette. The video cassette box is also labeled on the short edge. (See labeling diagram - Appendix 6)

11.1.2 Each diskette is labeled with the diskette number (which is identical to the video cassette number) and the participant identification numbers. The diskette is placed with its matching video cassette for shipping. (See labeling diagram - Appendix 6)

11.2 Content of Mailing

Each weekly mailing from the field centers to the Ultrasound Reading Center contains:

a. Video cassettes for the participant ultrasound studies completed the previous week.
b. Diskettes containing the participant files for the ultrasound studies completed the previous week.
c. Diskettes containing the blood pressure files for the ultrasound studies completed the previous week.
c. A copy of the week's log sheet. (See Appendix 5)
e. A copy of the Shipping Log sheet for the week.
f. A video cassette containing phantom scan(s), if appropriate.
g. Biosound Service Report, if appropriate.

11.3 Frequency of Mailing

The video cassettes, diskettes and lists described in Section 11.1 are mailed each week no later than Tuesday afternoon to the Ultrasound Reading Center. The Ultrasound Reading Center needs to receive these cassettes no later than Wednesday afternoon.

11.4 Package Labeling

The address label from each field center has the following information:

a. Field center personnel sending the package.
b. Field center return address.
c. The shipping number from the Shipping Log sheet.
d. Address label to the Ultrasound Reading Center:

Ultrasound Reading Center
4310 Enterprise Drive, Suite C
Winston-Salem, North Carolina 27106

Mailing is by services guaranteeing package arrival at the Ultrasound Reading Center no later than mid-afternoon on the Wednesday following the mailing.

11.5 Verification of Mailing Contents

The contents are verified upon receipt of shipment at URC. If there are any discrepancies, the field center will be notified.

12. POLICIES/PROCEDURES FOR REPORTING B-MODE ULTRASOUND RESULTS

12.1 Routine Reporting

12.1.1 Routine Report by Field Center to Participant

A clinic visit report is issued by the field center, informing the participant that an evaluation will be made of the ultrasound examination and that further notification will be made ONLY in the case of unusual findings. A sample letter appears below.

"Portions of the carotid arteries (blood vessels in the neck) were measured. We will contact you (and your physician) if the opening of an artery is narrowed to 2 millimeters or less.

12.1.2 Routine Report from Ultrasound Reading Center to Field Center

The ultrasound report to each field center is a weekly list of participant studies read the previous week and an alert designation whenever an alert condition was detected at the Ultrasound Reading Center. The list will consist of the following information:

a. Participant Identification numbers
b. Participant last name, first and middle initial
c. Date of birth
d. Race and gender
e. Examination date
f.. Alert (Yes or Blank)

12.2 Procedures for Non-routine Results

12.2.1 If lumen narrowing to 2 mm or less is detected by the sonographer:

The sonographer identifies a study as a possible alert and notes the reason on the log sheet. The URC identifies the study for review and confirmation by the URC ultrasound clinician. Such reviews take place on a regular basis, prior to the routine reading by URC readers.

12.2.2 If lumen narrowing to 2 mm or less is detected by the reader:

The study will proceed through the routine reading process. The reader identifies a study as a possible alert. The study is reviewed by the URC ultrasound clinician. Such reviews take place on a regular basis.

12.3.1 Report from Ultrasound Reading Center to Field Center

A report is sent by the URC to the field center listing all studies for which possible alerts were cited by the sonographer. This report will indicate which studies were and were not confirmed as alerts.

12.3.2 Reporting of Confirmed Alerts by the Ultrasound Reading Center to Field Center

A report is sent by the URC clinician to the field center with a brief evaluation. The field center then contacts the participant and the participant's provider of medical care. The URC sends a report summarizing the findings of the clinician, whether an abnormality was identified and, where appropriate, to suggest a clinical evaluation.

12.3.3 Reporting of Confirmed Alerts by the Field Center to the Participant

An examples of a letter to send to the participants in whom a carotid ultrasound alert value is confirmed appear below.

Alert for lumen narrowing to 2 mm or less:

"As a participant in the ARIC Study, you had a B-mode ultrasound examination to measure the carotid arteries (blood vessels in your neck). During that examination, narrowing of the of the vessel was found in the _____ artery(s). Such narrowing is most often associated with atherosclerosis (hardening of the arteries). While some narrowing is found in many people, the amount of narrowing identified on your study was greater than expected (residual lumen of 2 mm or less). We recommend that you consult with your physician to determine whether further evaluation or treatment is necessary. If you do not have a personal physician the ARIC office will be happy to work with you to arrange for a referral."

13. PARTICIPANT SAFETY PRECAUTIONS

See Manual 2.

APPENDIX I: DOPPLER SIGNAL IDENTIFICATION OF THE INTERNAL CAROTID ARTERY

It is important to carefully distinguish between the internal and external carotid arteries using two criteria. First, the internal normally has a significantly larger diameter than the external; second, the blood flow velocity pattern in the two vessels as determined with Doppler ultrasound is distinctly different. Used together, these two considerations permit the internal carotid artery to be identified with a high degree of confidence.

Although tributaries originating from the external carotid artery may occasionally be viewed with B-mode ultrasound to help in this differentiation, Doppler ultrasound in most cases is more efficient and specific for this separation. The method and criteria for this identification are as follows:

A B-mode image is obtained of the carotid bifurcation where the common carotid artery divides. In some instances, the best anatomical angle will show the flow divider as well as the proximal internal and external carotid arteries. In the remaining cases, the flow divider and only one vessel can be seen from a single angle. In those instances, the other artery can be visualized by gently rocking the ultrasound transducer back and forth in angle or position or both. Doppler is used to differentiate internal and external carotid arteries in these instances.

To obtain a Doppler sample of each artery, press the DOP CUR button on the instrument panel and using the tracking ball on the instrument panel move the Doppler cursor so that it is positioned within the lumen of the branch farthest from the skin surface. The DOP button is pressed. The sonographer observes the tracing on the left monitor and listens to the Doppler signal by turning up the audio on the instrument panel. If the ultrasound transducer is in the internal carotid artery, the flow pattern will be that of a low-resistance bed. This signal has a rapid upstroke and a quasi-steady flow through systole and diastole. The flow continues throughout the cardiac cycle and begins to increase again at the next systole.

Flow directed toward the head and away from the heart throughout the cycle is represented as a tracing above the baseline in Figure 15. If the Doppler signal does not correspond to the expected pattern, the cursor is placed within the other branch of the common carotid artery. The external carotid artery is usually nearer the skin surface when viewed from an anterior angle and is a high-resistance vessel. The characteristics of Doppler signal in this vessel are a forward flow with a sharp upstroke and sometimes a high-resistance artery is cessation of flow before the onset of the next systole as defined in Figure 16. A Doppler signal for a combination of internal and external carotid flow patterns is illustrated in Figure 17.

The extent to which the Doppler effect "occurs" depends upon the relative orientation of the direction of blood flow and the direction of propagation of the ultrasound pulse. If the two directions are parallel, the effect is maximum. If the directions are perpendicular, in principle NO DOPPLER EFFECT WILL OCCUR.

While it is impossible get the directions of ultrasound propagation and blood flow exactly parallel, they should be as close to parallel as possible in order to obtain a strong Doppler signal. Regardless of whether the sidelooking or inline Doppler functions are used, the two directions must NOT BE PERPENDICULAR.

APPENDIX II: SOFTWARE TROUBLESHOOTING

Common Problems and Their Solutions

Listed below are some problems you could encounter, and some suggestions on how to correct them.

At the C:> prompt, type **aricscan** and press the ENTER key.

The message **bad command or file name** indicates that an incorrect command was entered. Correct the spelling and try again.

C:>Date

If the correct date appears, press the ENTER key. If the date displayed is incorrect, type in the correct date using the exact format displayed on the computer screen. Example: **01-14-93**

C:>Time

If the correct time appears, press the ENTER key. If the displayed time is incorrect, type in the time of day using the exact format displayed on the computer screen. Example: **10:30**

Demographic screen entries:

Participant ID: Six digits must be entered. If a digit is left off, it must be entered to continue or backspace to correct entire ID.

Visit: Two digits must be entered. Example: 07 referring to Visit 03. If one digit is entered, the computer waits for the second digit.

Sonographer: Three digits must be entered. If two or less digits are entered, you will not be able to continue. If by accident a fourth digit is pressed, an ERROR screen appears. Press the ENTER key. The demographic screen reappears. Corrections can be made at this time by using the backspace key.

Cassette: The identification of the tape will automatically appear on the demographics screen. (the tape has to be put in before this screen) Verify tape in VCR and screen ID's match.

Initials: Enter the participant's first and middle initials. If the participant has no middle initial, enter the one initial and press ENTER. To insert a period for no initial press ENTER again. Once the period appears press ENTER again to move to the next field. If it is necessary to make a correction, use the left arrow key to return to the INITIALS column to make corrections.

Last Name: Type only the first five digits of the participant's last name and press the ENTER key. No more than five digits will be recorded on file.

Gender: Enter **F** or **M**. If a different letter is entered, an ERROR message appears. Press the ENTER key and type in the correct entry.

Race: Enter B, W or O. If something different is entered, an ERROR message appears. Press the ENTER key and type in the correct entry.

Date Of Birth: Type in the participant's date of birth. If a nonexistent number of a month or day is entered, for example: **14/12/32**, or **12/32/32**, an ERROR message appears. Press the ENTER key and type in the correct date of birth.

Note: If an incorrect date of birth that is a valid date is entered, the sonographer is responsible for correcting it at the verification screen.

Note: The backspace key can be used to make corrections until the ENTER key is pressed.

Note: If you are at the end of the demographics screen and notice an incorrect entry, use the left arrow key to toggle back to make the necessary corrections.

Common Problems Associated With the Scanning Screen:

If the NEXT SITE footswitch is pressed instead of the SELECT footswitch for a particular site, the program will toggle forward. You can immediately correct for this by pressing the PREVIOUS SITE on the sonographer's box to toggle back to the skipped site, and then tone the image using the SELECT foot switch.

Accidently pressing the SELECT instead of NEXT SITE before pressing RECORD on the sonographer's box will cause the computer monitor to blink for 5 seconds. The study flow screen will return after the blinking stops. The screen will read "Press RECORD" on the sonographer's box. A **WAIT** message appears while the VCR is automatically put into record by the computer.

Software appears to be "Hung":

When the **software will not respond to the input commands** - the scan can be continued by following these steps:

1. fast forward the tape to the end of recorded space
2. press RECORD on the VCR key pad
3. verbally identify the SELECT and NEXT SITE segments on the tape
4. Note on logsheet for this tape to be re-striped.
5. Record answers to questions that would normally be on the US screens:
   - Lesion
   - Sonographer impression
   - Distensibility Code
   - Deviations in Protocol (i.e. B-mode, BP and Distensibility)

Wait Screens: If the wait screen seems hung, it has a time out feature - after 2 minutes the software will issue the command to retry the procedure.

A **"Rewind for 8 seconds and ENTER"** message appears when the VCR and computer have lost the address and does not know what section of the tape it is at. Sometimes this step will have to be repeated more than once. Be

sure the rewind 8 seconds starts with recorded space on the tape. The counter will count backwards when rewinding in a recorded space.

Pause & Record mode on VCR:

If VCR is in the **PAUSE & RECORD** mode and does not release to **RECORD** only, press the **PAUSE** key on the VCR key pad to release it manually. The program will then proceed through the flow of the scanning program. The VCR will then go into RECORD and you can continue with the scan.

Comment Screen (appears hung):

If the screen is blank with no "COMMENTS" heading, the sonographer should enter the comments and press **ENTER** to continue through the program.

To Check Header File:

To change directory to ARIC at the **C:>** type **cd(space)ARIC** <ENTER> At **C:\ARIC>** type**(space)header** and 2 four digit #'s will be displayed. The first four digits are the tape number and should match the tape being used; or, if a new tape is to be used the # should be **one less** than the new tape number.

If the tape number matches the tape being used no edit is needed. At the **C:\ARIC>** type **cd(space)** <ENTER> to return to the root directory. Begin new scan.

If the tape number does not match the tape being used do the following: At the **C:\ARIC>** type **edit(space)header** <ENTER>. A menu driven program will display the file. Use the **arrow keys** to move the cursor to the tape number. Insert the correct number and delete the old number by using the delete key.

When changes are completed - press **Alt(key)+ F(key)** to get the file menu. Press **X** to exit. A gray menu box will appear and ask if the changes are to be saved. Press **Y** and <ENTER>. This will return you to the **C:\ARIC>**. Type **cd(space)** <ENTER>. Begin new scan.

Select light is on at the beginning of a scan:

If the Select light is on at the beginning of a scan, it must be **reset** before that scan can be performed. To reset the select light - At the **C:\>** type **cd(space)test** <ENTER>. At **C:\TEST>** type **initff** <ENTER>. This will cause the select light to go off. Then, at **C:\TEST>** type **cd(space)**<ENTER> to return to the root directory of the computer.

APPENDIX III: TROUBLESHOOTING

Phase 2 Setup

The instructions on the Phase 2 right monitor suggests that any key can be pressed to display the main menu. However, if the letter "D" is not pressed at that point, the Phase 2 cannot be placed in debug mode without first shutting down all of the equipment. If shutdown is necessary, follow instructions in Section 6 to startup the equipment.

If the PROBE 2 key is pressed, a No Probe message appears. Press the PROBE 1 key to continue.

If a wrong menu key is pressed, press the ESCAPE key, located on the Phase 2 keyboard, to return to the previous menu.

At any time during the setup, it is discovered that the participant's name or I.D. is incorrect, press the ESCAPE key until the main menu screen returns. Press the 4th menu key to display Setup. Press the first menu key for Patient menu. Press the first or second menu key to correct the patient information. Once in the Name or Participant I.D. menu, the CLEAR key, located on the Phase 2 keyboard, can be used to clear an incorrect entry.

Remember that the DOP CURSOR key is used as a toggle. It can remove or return the cursor at any given time.

If the Doppler doesn't work well - check cursor alignment with blood flow (see Appendix I) and the focus setting. It should be aligned to the cursor - artery. Check for Bubbles in transducer. Focus and bubbles in the transducer greatly affect both Doppler and Distensibility.

To ensure that the image orientation is in "standard" mode, the following should be completed daily:

Select Image Control Options
Select TGC
Select Standard
Press **ESCAPE** to exit out to Main Menu

In the event that the equipment still fails to operate as designed, call the Biosound technician for assistance.

APPENDIX IV: BIOSOUND KEYBOARD

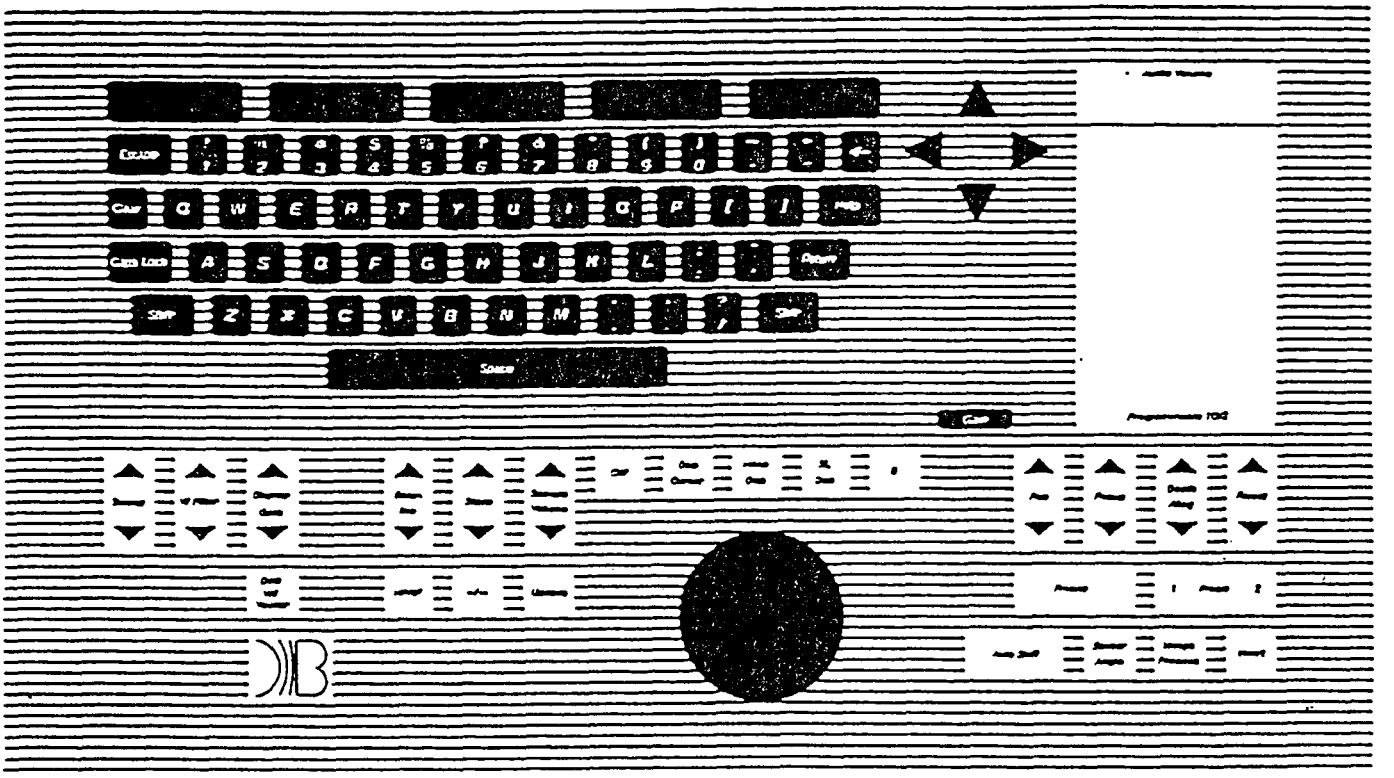


Figure 1

APPENDIX V: LOG SHEET REFERENCE

♦A For field center use to record evaluation record/notices from the URC

♦B Place cassette ID label here

♦C Participant ID#

♦D Participant date of birth

♦E Participant's last name, first initial, then middle initial

♦F Record actual scan date (mm/dd/yy)

♦G VCR start time
* VCR stop time only needs to be recorded when the last participant on the tape is scanned.

♦H Sonographer ID #
Sonographer Impression: P - Poor
F - Fair
G - Good
E - Excellent

♦I List QC site scanned

♦J List tracking impression. If no tracking is done, list reason.

♦K Yes/No. List sites not completed.

♦L Any information pertinent to interpretation of images or following flow of scan, equipment problems, or imaging problem, etc.

♦ Repeat Codes -

1. Actual repeat scans of a site need to be identified on the log sheet only.

2. If a code is repeated because the select footswitch was not pressed to advance the flow chart, note on the logsheet the circumstances. The sites do not need to be repeated. Once identified, the URC will correct the file to match the images on tape.

♦M Starting Date and Shipping Number

Beginning Shipping Numbers for each field center are as follows:

Forsyth ARIC/FHS:	FU3001
Jackson ARIC:	JU3001
Minneapolis ARIC/FHS:	MU3001

Hagerstown ARIC: WU3001

- Login report to Field Center - this report acknowledges the receipt of studies and processing is complete for the Login procedures. This report is sent weekly. The sonographers can delete the studies listed from the studies directory on their PC. This needs to be done weekly to prevent hard drive disk space problems.

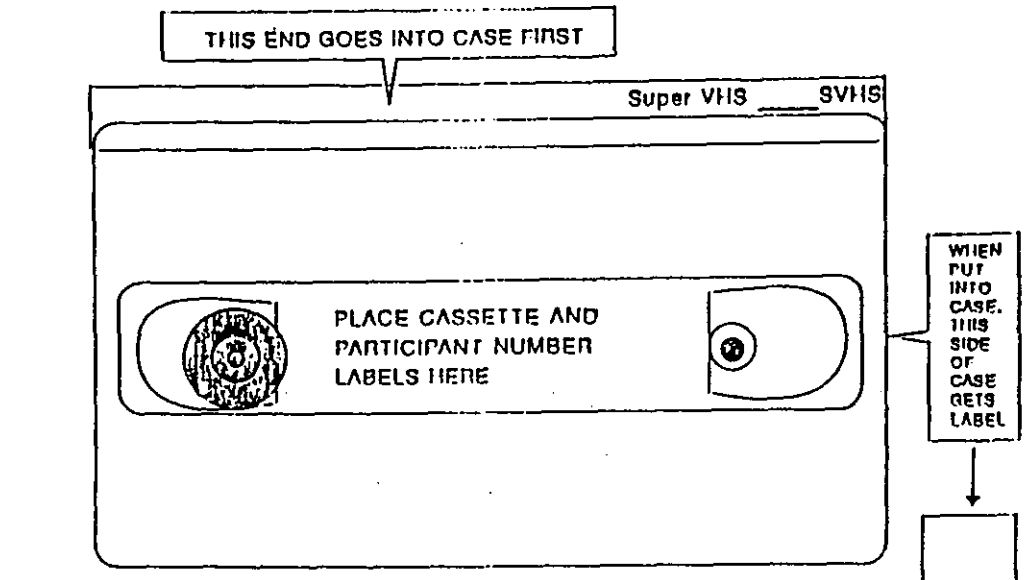
LOG SHEET

Week/Shipping #: ♦N _____ Page _____

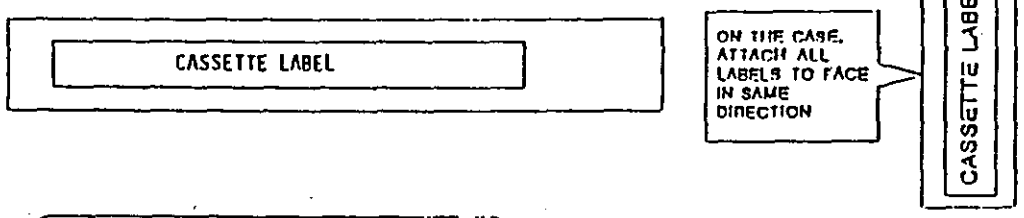
EVAL NEED	CASSETTE ID	PARTICIPANT ID, NAME, SIZE AND STUDY	SCAN DATE	REC VCR SIDE/STP	SONO #/INP	QC SIZE	TAE INP NEE	INC STUDY	
♦A	♦B	♦C ♦D ♦E ♦F	♦G	♦H	♦I	♦J	♦K	Circle Y N ♦L	♦M
								Circle Y N	
								Circle Y N	
								Circle Y N	

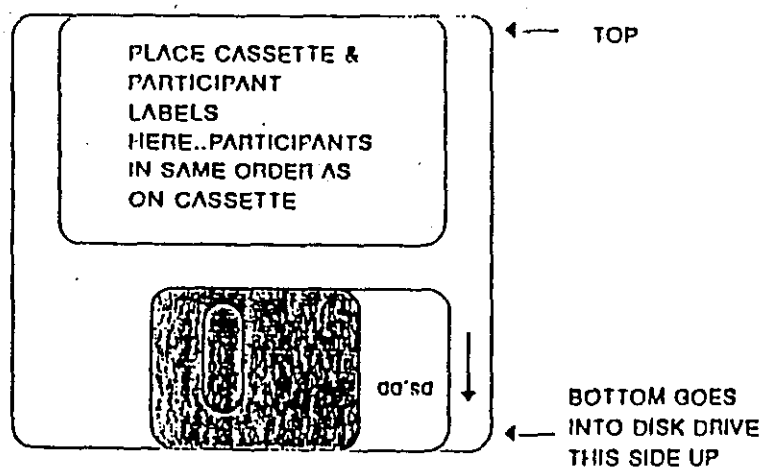
Field Center Ultrasound Log Sheet

APPENDIX VI: VIDEO CASSETTE AND DISKETTE LABELING DIAGRAM


THIS END GOES INTO CASE FIRST
Super VHS
SVHS
PLACE CASSETTE AND PARTICIPANT NUMBER LABELS HERE
WHEN PUT INTO CASE, THIS SIDE OF CASE GETS LABEL
CASSETTE LABEL

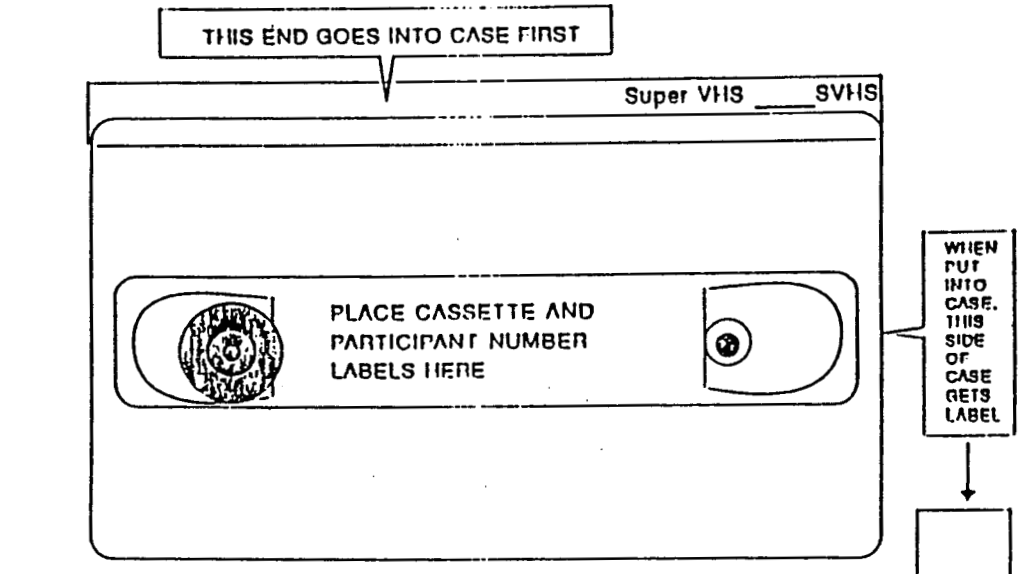
SUPER VHS CASSETTE LABELING



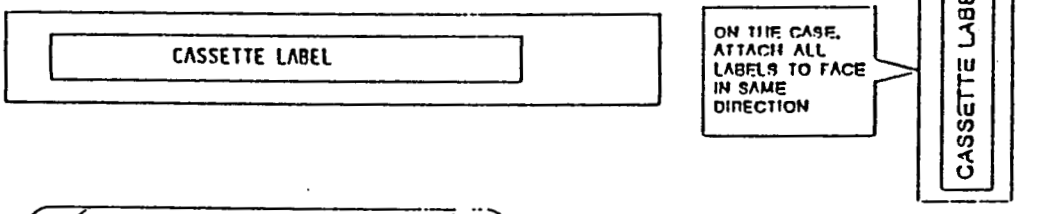

PLACE CASSETTE & PARTICIPANT LABELS HERE..PARTICIPANTS IN SAME ORDER AS ON CASSETTE
TOP
BOTTOM GOES INTO DISK DRIVE THIS SIDE UP

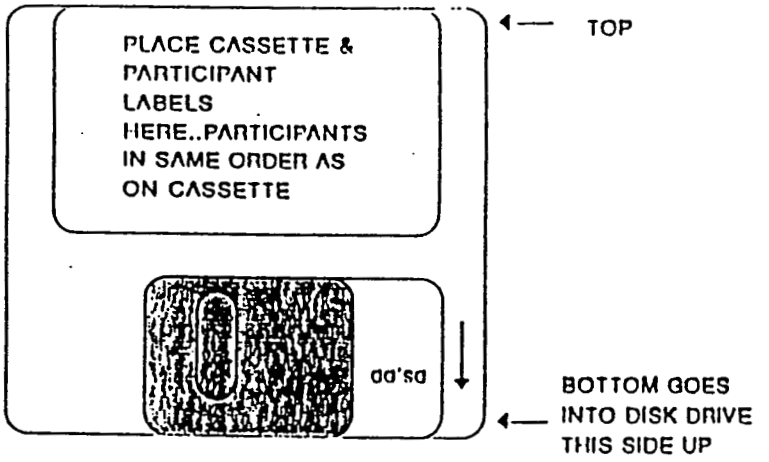
3 1/2 INCH DISK LABELING

APPENDIX VI: VIDEO CASSETTE AND DISKETTE LABELING DIAGRAM

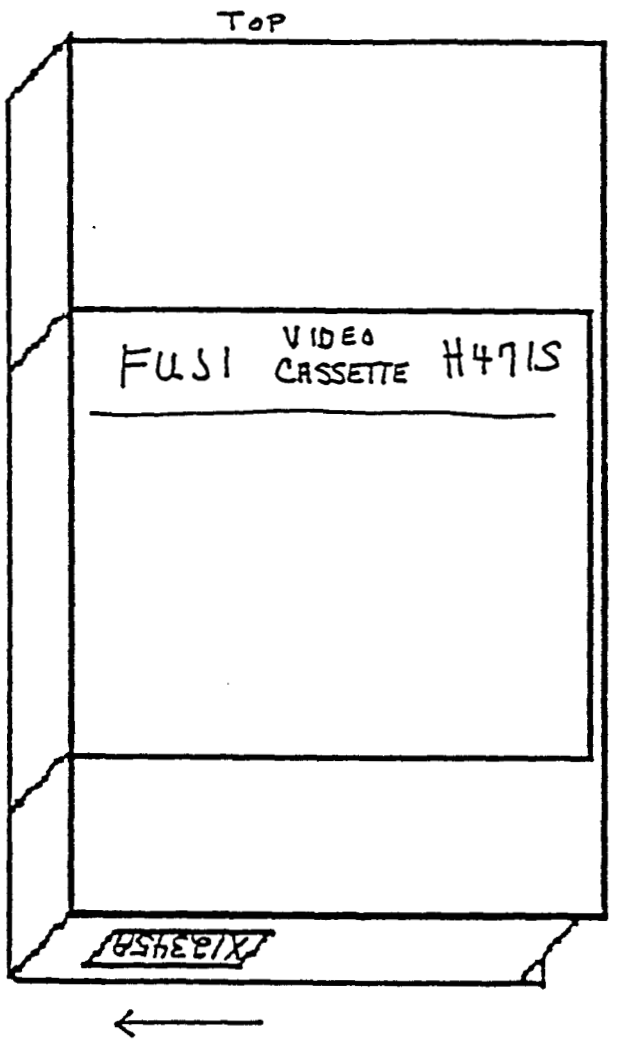

THIS END GOES INTO CASE FIRST
Super VHS ____SVHS
PLACE CASSETTE AND PARTICIPANT NUMBER LABELS HERE
WHEN PUT INTO CASE, THIS SIDE OF CASE GETS LABEL
CASSETTE LABEL

SUPER VHS CASSETTE LABELING




PLACE CASSETTE & PARTICIPANT LABELS HERE..PARTICIPANTS IN SAME ORDER AS ON CASSETTE
TOP
BOTTOM GOES INTO DISK DRIVE THIS SIDE UP

3 1/2 INCH DISK LABELING


TOP
FUJI VIDEO CASSETTE H471S

APPENDIX VII: WEEKLY SHIPPING LOG

WEEKLY SHIPPING LOG

SHIPPING LOG

1. SHIPPING NUMBER:_____

2. NAME OF SHIPPER:_____

3. SHIPPING TO:_____

4. REPORTING PERIOD:

   STARTING DATE: __/__/__ (mm/dd/yy)

   ENDING DATE: __/__/__ (mm/dd/yy)

5. NUMBER OF ITEMS:

	TYPE OF ITEM	NUMBER SENT	NUMBER RECEIVED
A.	DATA DISKETTES		
B.	12 LEAD ECG PAPER TRACINGS		
C.	PAPER ECG RHYTHM STRIPS		
D.	PARTICIPANT BLOOD SAMPLES		
E.	ULTRASOUND VIDEO CASSETTES		
F.	BACKUP TAPE CARTRIDGE		
G.	PAPER FORMS (LIST TYPE)		
	_____		
	_____		
	_____		
	_____		
	_____		

6. COMMENTS CONCERNING SHIPMENT CONTENTS:_____

_____

7. SENT: DATE: __/__/__ TIME __/__/__ AM/PM

8. INITIALS OF STAFF MEMBER PREPARING SHIPMENT: __ __ __

****

9. COMMENTS ON CONDITION OF TOTAL SHIPMENT ON ARRIVAL:_____

_____

10. ARRIVE: DATE: __/__/__ TIME: __/__/__ AM/PM

11. INITIALS OF STAFF MEMBER RECEIVING SHIPMENT: __ __ __

APPENDIX VIII: INFORMATION REFERENCE SHEET

I. List of contact personnel when experiencing equipment or procedure failure during the ultrasound scan.

Before contacting the individual by phone, make a list of the specific problem -- symptom, include the date symptom started and date service was requested. Fax this list to your contact person and fax a copy to the URC attention Delilah Cook, Chief Reader and Carolyn Bell - login. Follow-up on service by sending a summary of results by computer network mail, U.S. mail, or fax (preference of the field center) to URC.

1. Biosound 800-428-7378 Fax # 317-841-8616

   Phase 2 Unit only

   Bob Nitch
   Dave Struewing
   Mike Meador

2. URC 919-759-2137 Fax # 919-759-2139

Peripheal Equipment -
Sonographer box, attached foot switches and cables, ultrasound software, the arterial tracker and transducer arm (at centers where applicable).

Sonographer certification and training, and data flow

Kathy Joyce, Administrative Secretary who will direct call as follows:

Delilah Cook - Protocol procedure, Sonographer Training and Data Flow, or equipment problems
Carolyn Bell -- Login and Distensibility
Pam Wells or Delilah Cook - Sonographer Certification and Review

3. Dell Computers Damian Brown
   800-284-1200 ext. 3967

   or local compouter repair facility

4. Dinamap **Johnson & Johnson Critikon**
   Pam Thornbury
   800-255-2500 or 919-852-2733

5. Oscilloscope **Tektronix**
   700 Professional Drive
   Gathersburg, Maryland 20879

6. Strip Chart Recorder **MFE Instruments**
   John Lepore
   800-472-4633 Fax # 508-921-9110

II. Miscellaneous Equipment Information

1. Dinamap -- calibration and alarm settings are Pre-set at the factory and do not need any action from the sonographer -- factory settings are acceptable for our purpose.

2. S-VHS tape - Do not purchase "Sony" brand tapes because the NEC-VCR is very sensitive and does not operate properly with this brand. Due to storage limitation at the URC, the Fuji tape has been tested and is recommended for this study.

APPENDIX IX: READING LIST

"The Language of Anatomy"
From: Gardner, W.D. & Osburn, W. A. (1973) Structure of the Human Body. (2nd ed.) Philadelphia: W.B. Saunders Company.

"Angiology"
From: Williams, P.L. and Warwick, R., eds. (1980) Gray's Anatomy. (36th ed) Philadelphia: W.B. Saunders Co.

"Blood Supply to the Head and Neck"
From: Fried, L.A. (1976) Anatomy of the Head, Neck, Face, and Jaws. Philadelphia: Lea & Febiger.

"Systemic and Pulmonary Circulations"
From: Underhill, S.L., Woods, S.L., Sivarajan, E.S. and Halpenny. C.J., eds. (1982) Cardiac Nursing. Philadelphia: J.B. Lippincott Co.

"Pathogenesis of Atherosclerosis"
From: Cardiac Nursing.

"The Carotid Plaque"
From: Robicsek, F. Ed. (1986) Extracranial Cerebrovascular Disease Diagnosis and Management. NY: McMillan Publishing.

Diagnostic Ultrasound, Principles, Instruments, and Exercises by Frederick W. Kremkau, Ph.D. Third Edition Publisher: W. B. Saunders Company Harcourt Brace Jovanovich, Inc.

Chapter 1 from Diagnostic Ultrasound;
Frederick W. Kremkau, Ph.D. 3rd edition.

Chapter 2, pages 9-30 in Diagnostic Ultrasound.

Chapter 2, pages 41-45 of Diagnostic Ultrasound.

Chapter 3 of Diagnostic Ultrasound.

Chapter 4 pages 105-114 and pages 130-137 of Diagnostic Ultrasound.

"How a B-Mode Image is formed - A Summary".

Chapter 5 in Diagnostic Ultrasound.

Article, "Artifacts in Ultrasound Imaging" (Kremkau & Taylor)

Chapter 6 in Diagnostic Ultrasound. Skip Section 6.3.

Chapter 7 in Diagnostic Ultrasound. Skip Section 7.3.

Pignoli, P., Termoli, E., Poli, A., Oreste, P., Paoletti, R. (1986) "Intimal Plus Medial Thickness of the Arterial Wall: A Direct Measurement with Ultrasound Imaging." Circulation. 74 (6), 1399-1406.

Fact Sheet on Heart Attack, Stroke, and Risk Factors. (1987) American Heart Association. Dallas, TX.

Pages 132-143 "Coronary Artery Disease Risk Factors" From: Cardiac Nursing

Coronary Risk Factor Statement to the American Public. (1987) American Heart Association. Dallas, TX.

Grundy, S.M. (1986) Cholesterol and coronary heart disease. JAMA. 256 (20) 2849-2858.

Eron, Carol (1988) Young hearts. Science News. 134, 234-236.

Stamler, J., Wentworth, D. & Neaton, J.D. (1986) "Is the Relationship Netween Serum Cholesterol and Risk of Premature Death From Coronary Heart Disease Continuous and Graded?" JAMA. 256 (20) 2823-2828.

Enos, W.F., Holmes, R.H. & Beyer, J. (1953) "Coronary Heart Disease Among United States Soldiers Killed in Action in Korea: A Preliminary Report." JAMA. 152, 1090-1093. (Reprinted 1986 JAMA 256 (20).

Articles of Interest

"High Resolution B-Mode Ultrasound Scanning Methods in the Atherosclerosis Risk in Communities Study (ARIC)", M.G. Bond et al. Journal of Neuroimaging, Vol 1, No 2, May 1991, pages 68-73.

"High Resolution B-Mode Ultrasound Reading Methods in the Atherosclerosis Risk in Communities (ARIC) Cohort, Ward A. Riley, et al. Journal of Neuroimaging, Vol 1, No 4, November 1991, pages 168-172.

"An Approach to the Noninvasive Periodic Assessment of Arterial Elasticity in the Young" Riley, Barnes and Schey. Preventive Medicine 13, 169-184 (1984).

"Ultrasonic Measurement of the Elastic Modulus of the Common Carotid Artery: The Atherosclerosis Risk in Communities (ARIC) Study". Accepted by Stroke, 1992.